Nevada Rural Hospital Flexibility Program

Checklist for the Medicare Critical Access Hospital (CAH) Certification Survey

Please direct questions or comments about this checklist to:

John Packham, PhD
Director, Nevada Rural Hospital Flexibility Program
Nevada Office of Rural Health
University of Nevada School of Medicine / Mailstop 348
411 West Second Street
Reno, Nevada 89503-5308
Phone: (775) 784-1235 / Fax: (775) 784-1137

jfp@unr.edu

Last modification of this document: September 24, 2004

Table of Contents

Tag	Statute	Regulation	Page
	Overview	of the Checklist for the Medicare Critical Access Hospital (CAH) Certification Survey	ii
C150	§485.608	Condition of participation: Compliance with Federal, State, and local laws and regulations	1
C160	§485.610	Condition of participation: Status and location	2
C170	§485.612	Condition of participation: Compliance with hospital requirements at time of application	4
C190	§485.616	Condition of participation: Agreements	4
C200	§485.618	Condition of participation: Emergency services	6
C210	§485.620	Condition of participation: Number of beds and length of stay	12
C220	§485.623	Condition of participation: Physical plant and environment	14
C240	§485.627	Condition of participation: Organizational structure	21
C250	§485.631	Condition of participation: Staffing and staff responsibilities	22
C270	§485.635	Condition of participation: Provision of services	27
C300	§485.638	Condition of participation: Clinical records	58
C320	§485.639	Condition of participation: Surgical services	66
C330	§485.641	Condition of participation: Periodic evaluation and quality assurance	76
C344	§485.643	Condition of participation: Organ, tissue, and eye procurement	80
C350	§485.645	Special requirements for CAH providers of long-term care services ("swing-beds")	87
_	§485.647	Psychiatric and rehabilitation distinct part units	N/A

Overview of the Checklist for the Medicare Critical Access Hospital (CAH) Certification Survey

The following checklist draws on a number of existing documents including the interpretive guidelines for surveyors developed and revised by CMS, the Idaho self-audit tool developed by the Idaho Hospital Association, Nevada Administrative Code (NAC) Chapter 449, communications with the Nevada Bureau of Licensure and Certification (BLC), mock survey tools prepared by the Nevada Office of Rural Health and the Nevada Rural Hospital Partners.

This checklist or tool is designed for use by hospital administrators and staffs to ensure that they are as prepared as possible for the initial survey their hospital will undergo as part of the CAH application process. This checklist is also updated periodically – as changes in federal and state regulations take place – and is thus useful for CAH re-surveys. The tool is structured to conform to the most current version of the interpretive guidelines (April 2004) which State BLC surveyors will use in evaluating CAH applicant hospitals.

The checklist can also be used to see if the required standards are met or whether corrective action is needed. It is suggested that the tool be parceled out to the appropriate departments which can then report on their status in terms of meeting the outlined requirements.

The tool is divided into four columns, as follows:

- The first column (*Tag*) provides the number of the specific interpretive guideline which the surveyors use for this section.
- The second column (Regulation) lists the specific regulation which applies to that area.
- The third column (*Elements to Consider*) is our interpretation of the items the hospital must assess to ensure that the standards for that regulation are met. These "elements" were derived from the guidance to surveyors. In most cases, the context of the guidance was altered to make it read more appropriately for a "self check."

Notes or cautionary language has been added in areas which may present problems. These notes include changes in regulations and rules, as well as changes in the interpretation of such rules and regulations. The Nevada Office of Rural Health will forward notices of such changes to all rural hospitals in the process of Critical Access Hospital designation as soon as such notices are received.

In some places you are asked to "see policy" or "see sample agreement" – these sample policies and agreements are contained in the accompanying appendix: Nevada Rural Hospital Flexibility Program: Sample Agreements and Assurance Documents for the Critical Access Hospital Certification Survey.

• The fourth column (*Evidence/Surveyors' Focus*) indicates the types of evidence and focus undertaken by surveyors to determine compliance with standards and conditions. As such, this column services as a checklist for corrective action and steps which needs to be taken prior to the survey.

Although not specifically addressed in CAH regulations, nor in this tool, it is noted that hospitals also must be in compliance at the initial survey with federal regulations pertaining to advance directives, criminal background checks, and EMTALA.

As you proceed through this checklist and in anticipation of the certification survey, you and your staff should begin assembling the following materials (most are discussed in the detailed checklist below):

- ☐ Hospital policies and procedures covering all CAH statutory requirements, such as:
 - CAH Pharmacy Department Policies and Procedures Manual
 - CAH Laboratory Department Policies and Procedures Manual
 - CAH Emergency Department Policies and Procedures Manual
 - CAH Medical Records Policies and Procedures Manual
 - CAH Nursing Department Policies and Procedures Manual
 - CAH Dietary Policies and Procedures Manual
 - CAH Physical Plant and Maintenance Policies and Procedures Manual
 - CAH Organ, Tissue, and Eye Procurement Policies and Procedures Manual
 - CAH HIPAA Compliance Manual
- ☐ List of services the hospital provides directly
- ☐ List of services the hospital provides indirectly through arrangements or agreements

Copy of all service agreements and network agreements including participation in a communication system, physician coverage (if applicable), and referral, admission, and transportation of patients
- CAH Agreements and Contracts Binder
CAH Periodic Evaluation and Quality Assurance Plan, including CAH QA/QI meeting agenda and minutes
Hospital organizational chart and position descriptions for all levels of personnel – note: the organization chart should highlight, where applicable, the lines of authority within the distinct acute care, long-term care, and clinic operations of the facility
- CAH Organizational Chart
- CAH Job Description Binder
Staffing schedules for hospital emergency departments, outpatient/clinic department, and other units for the past three months
On-call schedules for physicians and other staff (e.g., mid-level providers, laboratory personnel, imaging) for the past three months
Hospital personnel files with evidence of appropriate licensure, certification, and/or registration
Credentials files for physicians and mid-level providers
Hospital committee meeting minutes for the past year
- CAH Infection Control Committee
 CAH Periodic Evaluation and Quality Assurance Committee
 CAH Policies and Procedures Committee
Hospital governing body or board meeting minutes for the past year
- CAH Bylaws
CAH Administrative Policies and Procedures Manual

 CAH Personnel Policies and Procedures 	
☐ Hospital infection control log	
☐ Incident reports for the past year	
☐ Hospital utilization review reports and follow-ups for the past year	
☐ Menus for one month for all diets offered at the hospital	
□ Current and closed medical records, including records for swing bed patients, if applicable – the surveyors will request specific record the survey	ls during
☐ Admission, discharge, and transfer information	
☐ Emergency room logs for the past year	

In conclusion, it must be emphasized that your facility is probably already in compliance with most of the regulations listed in this checklist, since many of these same regulations are required for licensure by the State of Nevada. Hospital administration and staff likely possess most of the documentation and assurances needed for CAH designation. Nevertheless, the purpose of the CAH survey process is to evaluate your facility's compliance with each of the conditions of participation in the most efficient manner possible.

If you have any questions or comments about this checklist, please contact:

John Packham, PhD Director, Nevada FLEX Program Nevada Office of Rural Health University of Nevada School of Medicine / Mailstop 348 411 West Second Street / Room 110 Reno, Nevada 89503-5308

Phone: (775) 784-1235 / Fax: (775) 784-1137

E-mail: jfp@unr.edu

Checklist for the Medicare Critical Access Hospital (CAH) Certification Survey

Checklist for the Medicare Critical Access Hospital Certification Survey

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C150	§485.608 Condition of participation: Compliance with Federal, State, and local laws and regulation. The CAH and its staff are in compliance with applicable	Is your facility in compliance with EMTALA, PSDA, and SMDA regulations? See all applicable regulations contained in Nevada	Pre-survey research & compliance previously determined by the Nevada Office of Rural Health via your hospital's completion of the "Preliminary Application for Eligibility Determination."
	Federal, State and local laws and regulations.	Administrative Code (NAC) Chapter 449, NAC 449.363	
C151	(a) Standard: Compliance with Federal laws and regulations. The CAH is in compliance with applicable Federal laws and regulations related to the health and safety of patients.	Is your facility in compliance with applicable Federal laws and regulations related to the health and safety of patients? For example, has the CAH been convicted of violating a Federal law such as denying people with disabilities access to care? Have satisfactory corrections been made to bring the CAH into compliance with that law? Surveyors are required to refer noted noncompliance with Federal laws and regulations to the appropriate agency having jurisdiction (e.g., accessibility issues, blood borne pathogens, universal precautions, TB control to OSHA, hazardous chemical and waste issues to EPA, etc.)	Pre-survey research & compliance previously determined by the Nevada Office of Rural Health via your hospital's completion of the "Preliminary Application for Eligibility Determination." □ Interview with CAH Administrator/CEO
C152	(b) Standard: Compliance with State and local laws and regulations. All patient care services are furnished in accordance with applicable State and local laws and regulations.	Are all state mandated policies and procedures in place? Are CAH professional specialists licensed and practicing in accordance with State of Nevada practice acts? Note: As a CAH your hospital is not subject to some hospital regulations, but if your hospital is applying for status as CAH surveyors may take the position that on date of survey you must meet all then existing conditions. See sample policy C152	Pre-survey research & compliance previously determined by the Nevada Office of Rural Health via your hospital's completion of the "Preliminary Application for Eligibility Determination." BLC will determine what professional specialists (i.e., physicians, mid-level providers) provide patient care services at the facility and review Nevada practice act requirements (e.g., supervision requirements).
C153	(c) Standard: Licensure of CAH. The CAH is licensed in accordance with applicable Federal, State and local laws and regulations.	See all applicable chapters contained in NAC Chapter 449.	Generally not a focal concern <u>unless</u> the facility is currently not licensed by the State of Nevada.

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C154	(d) Standard: Licensure, certification or registration of personnel. Staff of the CAH are licensed, certified, or registered in accordance with applicable State and local laws and regulations.	All staff required by the State to be licensed must possess a current license. The CAH must ensure that these personnel are in compliance with the State of Nevada's licensure laws. Examples of healthcare professionals that require licensure include: nurses, MD/DOs, physician assistants, dietitians, x-ray technologists, dentists, physical therapists, occupational therapists, respiratory technicians and facility administrators. All CAH staff must meet all applicable standards required by State or local law for CAH personnel. This would include at a minimum: (a) Certification requirements; (b) minimum qualifications; and (c) training/education requirements. Are required fingerprint and reference checks on file? Have clearances been obtained from the Nevada Highway Patrol? See sample policy C154	Written documentation & review of policies & procedures: □ Binder – CAH Job Descriptions □ Current personnel files and staff licensure □ Personnel files are in compliance with facility and state policy □ CAH Personnel Policies and Procedures Manual
C160	§485.610 Condition of participation: Status and Location.	This COP only applies to initial surveys.	Pre-survey research & compliance previously determined by the Nevada Office of Rural Health via your hospital's completion of the "Preliminary Application for Eligibility Determination."
C161	(a) Standard: Status. The facility is a public or nonprofit hospital. The facility is — (1) A currently participating hospital that meets all COPs set forth in this subpart; (2) A recently closed facility, provided that the facility (i) was a hospital that ceased operations on or after the date that is 10 years before November 29, 1999; and (ii) meets the criteria for designation under this subpart as of the effective date of its designation; or (3) A health clinic or health center (as defined by the State) that (i) is licensed by the state as a health clinic or health center; (ii) was a hospital that was downsized to a health clinic or a health center; and (iii) as of the effective date of its designation, meets the criteria for designation set forth in this subpart.	Note: This regulation has changed per the BBRA (1999) – for profit hospitals are also eligible.	Pre-survey research & compliance previously determined by the Nevada Office of Rural Health via your hospital's completion of the "Preliminary Application for Eligibility Determination."

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C162	(b) Standard: Location in a Rural Area or Treatment as Rural. The CAH meets the requirements of either paragraph (b)(1) or (b)(2) of this section. (1) The CAH meets the following requirements: (i) the CAH is located outside any area that is a Metropolitan Statistical Area, as defined by the Office of Management and Budget, or that has been recognized as urban under §412.62(f) of this chapter; (ii) the CAH is not deemed to be located in an urban area under §412.63(b) of this chapter; and (iii) the CAH has not been classified as an urban hospital for purposes of the standardized payment amount by CMS or the Medicare Geographic Classification Review Board under §412.230(e) of this chapter, and is not among a group of hospitals that have been redesignated to an adjacent urban area under §412.232 of this chapter. (2) The CAH is located within a Metropolitan Statistical Area, as defined by the Office of Management and Budget, but is being treated as being located in a rural area in accordance with §412.103 of this chapter.	 Urban or metropolitan hospitals are "treated as rural" if one or more of the following apply: The hospital is located in a rural census tract of an MSA as determined by the most recent version of the Goldsmith Modification; or The hospital is located in an area designated as a rural area by any law or regulation of the State in which it is located; or The hospital is designated as a rural hospital by State law or regulation; or The hospital would qualify as a rural referral center if the hospital were located in a rural area; or The hospital would qualify as a sole community hospital if the hospital were located in a rural area. 	Pre-survey research & compliance previously determined by the Nevada Office of Rural Health via your hospital's completion of the "Preliminary Application for Eligibility Determination." NORH will provide assurances to the Bureau of Licensure and Certification prior to the survey that Metropolitan or Urban CAHs meet one or more of the criteria to be "treated as rural."
C165	Standard: Location Relative to Other Facilities or Necessary Provider Certification. The CAH is located more than a 35 mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15 mile drive) from a hospital or another CAH, or the CAH is certified by the State as being a necessary provider of health care services to residents in the area.	Note: Effective January 1, 2006, the NORH will no longer be able to designate facilities as "Necessary Providers of Health Care Services." Those CAHs designated as necessary providers prior to January 1, 2006 will retain the necessary provider waiver issued by the State of Nevada. One may reasonably consider a road "secondary" if it is not an Interstate, U.S., or State highway.	Pre-survey research & compliance previously determined by the Nevada Office of Rural Health via your hospital's completion of the "Preliminary Application for Eligibility Determination" and the application for designation as a "Necessary Provider of Health Care Services." NORH will provide assurances to the Bureau of Licensure and Certification prior to the survey that facilities meet this location requirement.

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C170	§485.612 Condition of participation: Compliance with hospital requirements at time of application. Except for recently closed facilities as described in §485.610(a)(2), or health clinics or health centers as described in §485.610(a)(3), the facility is a hospital that has a provider agreement to participate in the Medicare program as a hospital at the time the hospital applies for designation as a CAH. The hospital has a provider agreement to participate in the Medicare program as a hospital applies for designation as a CAH.	This COP applies only to initial surveys. All facilities applying to be a CAH must be (1) surveyed for hospital licensure in the State of Nevada and (2) be surveyed and certified as a Medicare Provider prior to being surveyed and certified as a CAH. This is an important condition. Be sure that you can demonstrate corrective action has been taken with regards to any deficiencies under old conditions of participation. NORH will assist your facility with a review of your last survey report, plan of correction, and follow-ups.	Written documentation: □ Provider agreement on file □ Review last SOD □ Corrections made/implemented per last POC
C190	§485.616 Condition of participation: Agreements.	What kind of agreement/system is set up to handle communications with transfer hospital? What about "back-up" systems? If your facility does not have a hospital-based SNF, do you have transfer agreements with another SNF? See sample agreements C190 and C192	Review of following document(s): Binder – CAH Agreements and Contracts
C191	(a) Standard: Agreements with network hospitals In the case of a CAH that is a member of a rural health network as defined in §485.603 of this chapter, the CAH has in effect an agreement with at least one hospital that is a member of the network for —	Section 485.603 defines a rural health network as an organization that includes at least one hospital that the State has designated or plans to designate as a CAH, and at least one hospital that furnishes acute care (hospital) services. How does or will the CAH participate with other hospitals or facilities in the network communication system? Is a communication log kept at the facility? Are there any difficulties in contacting network members? How are such difficulties dealt with? See sample agreements C190 and C192	Review of following document(s): □ Binder – CAH Agreements and Contracts □ Documentation of membership in NRHP Interviews with staff
C192	(1) Patient referral and transfer;	See sample agreements C190 and C192	Written documentation: □ Binder – CAH Agreements and Contracts

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C193	(2) The development and use of communication systems of the network, including the network's system for the electronic sharing of patient data; and telemetry and medical records, if the network has in operation such a system; and	How does the CAH participate with other hospitals and facilities in the network communications system? Is a communications log kept at the facility? Ask staff if there have been difficulties in contacting network members. If so, ask how the CAH deals with communications delays. What evidence demonstrates that CAH staff can operate communications equipment? How does the network's communications system compare with any online and available communications equipment in the CAH? When the network communications system is down how does the CAH communicate and share patient data with network hospital? See Sample Communications Agreement Between NORH/University of Nevada School of Medicine (UNSOM) and CAH (C193)	Written documentation: Agreement on file Communications log Backup system in place
C194	(3) The provision of emergency and non-emergency transportation among the facility and the hospital.	See sample agreement between CAH and local EMS provider (C194). See also NAC 449.331	Written documentation: Agreement between CAH and local EMS service on file
C195	(b) Standard: Agreement for credentialing and quality assurance. Each CAH that is a member of a rural health network shall have an agreement with respect to credentialing and quality assurance with at least — (i) One hospital that is a member of the network; or (ii) One QIO or equivalent entity; or (iii) One other appropriate and qualified entity identified in the State rural health care plan.	Surveyors will review any agreements related to credentialing or quality assurance to determine the level of assistance to be provided and the responsibilities of the CAH. Note: As of September 1, 2004, all CAHs and prospective CAHs must enter into an agreement with Nevada Rural Hospital Partners for quality assurance and credentialing. Any exception to this provision must be submitted to the Nevada Office of Rural Health in writing. See sample agreements C195 See also NAC 449.3628	Written documentation: □ Binder – CAH Agreements and Contracts – i.e., agreement between CAH and NRHP □ Documentation of follow-ups by identified entity

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C200 §485.618 Condition of participation: Emergency services. The CAH provides emergency care necessary to meet the needs of its inpatients and outpatients.		practice include maintaining compliance with applicable Fe all services provided in the CAH's emergency department, or established by nationally recognized professional organized	th acceptable standards of practice. Acceptable standards of ederal and State laws, regulations, and guidelines governing as well as any standards and recommendations promoted by zations such as the American Medical Association, American ergency Medicine, American College of Surgeons, American
		into its other departments in order to meet the needs and en that the CAH can immediately make available the full exter care for an emergency patient. Emergency Services integrat communication between the Emergency Department and ot emergency department patients to the services, equipment, (c) the immediate availability of services, equipment, perso emergency patients; and; (d) that the provision of services,	at demonstrate that its emergency services are truly integrated therefore care of its patients. The integration must be such an ergency care of its patients. The integration must be such at of its patient care resources to assess and render appropriate ion would include at a minimum: (a) coordination and ther CAH services/departments; (b) physical access for personnel, and resources of other CAH departments/services; nnel, and resources of other CAH departments/services to equipment, personnel and resources of other CAH within timeframes that protect the health and safety of patients are length of time it takes to transport the emergency patient erventions or diagnostic services will be rendered; and the for the staff from other departments to travel from their
		Time is critical in the provision of emergency care. The CA departments provide emergency patients the care and servic care situations, the time needed to provide the patient with significant effect on the patient. Delays in diagnosis and the affect the health and safety of patients who require emerger integration of its emergency services with its other department laboratory, etc) would not be in compliance with the Emergency	ses needed within safe and appropriate times. In emergency appropriate diagnostic and care interventions can have a e provision of needed interventions is likely to adversely acy care. Therefore, a CAH that cannot demonstrate ents (including radiological services, OR, intensive care,
		must be integrated into the CAH-wide QA program. The malaw, regulations, and guidelines, delineating the qualification	ns for the director of the CAH's emergency services in tice. The CAH's medical staff must establish policies and regency services or emergency department. Emergency and revised as necessary based on the ongoing monitoring or department QA activities. The CAH's emergency services edical staff must establish criteria, in accordance with State ons a medical staff member must possess in order to be ices. Qualifications include necessary education, experience

TAG REGULATION ELEMENTS TO CONSIDER EVIDENCE/SURVEYORS' FOO	US
C200 continued services. The CAH must staff the emergency department with the appropriate numbers and types of professionals and who possess the skills, education, certofications, specialized training and experience in emergency care to me written emergency procedures and needs anticipated by the facility. There must be sufficient medical and mu personnel to respond to the emergency medical needs and care of the patient population being served. The CAH must conduct of the determine the categories and numbers of MD/DOs, specialists, RNs, EMTs, and emergency department support and personnel to respond to the emergency procedures procedures and remove reads. The medical staff must establish criteria, in accordance law and regulations and acceptable standards of practice delineating the qualifications required for each cate emergency services staff (e.g., emergency physicians, specialist MD/DO, RNs, EMTs, mid-level practitioner. The CAH must conduct ongoing assessments of its emergency needs in order to anticipate the policies, process the needs of its inpatients and outpatients would include the provision of respiratory services an exceptable standards of practice. The scope of diagnostic and/or therapeutic respiratory services offered by the mergency patients. When respiratory services are provided those services must be provided in accordance vacceptable standards of practice. The scope of diagnostic and/or therapeutic respiratory services offered by the medical staff. The CAH must provide the approvide special qualified personnel necessary to furnish all services offered in a safe manner in accordance with acceptable spractice. There should be written policies for the delivery of any services provided. The policies and proced developed and approved by the medical staff and include the participation of any mid-level practitioners wor ED. The written policies should address the following services, as appropriate: (a) each type of service provide and whether they may perform it without supervise and proceding th	the the sing AH must but staff the with State ory of a etc.). It will be a compared to the co

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C201	(a) Standard: Availability. Emergency services are available on a 24-hour basis.	The CAH "makes available 24-hour emergency services". This does not mean that the CAH must remain open 24 hours a day when it does not have inpatients (including swing-bed patients). A CAH that does not have inpatients may close with no staff present, provided that it has an effective system in place to meet the requirement. The system must ensure that a practitioner with training and experience in emergency care is on call and immediately available by telephone or radio, and available on site within 30 minutes, (or 1 hour in certain frontier areas), 24 hours a day. Is there a qualified practitioner available 24-hours a day? Can that person be at the hospital within 30 minutes? Are required equipment, supplies and medications always readily available? Qualified practitioner need not be a doctor of medicine or osteopathy This practitioner could be NP or PA with the hospital's governing body's agreement. EMTALA is still a requirement for CAHs See sample policy C201	Review of following document(s): Binder – CAH Emergency Department Policies and Procedures ER log for the past year ER staffing schedules Review of open and closed patient records Facility inspection Interviews with staff, patients, and families and/or observations as applicable
C202	(b) Standard: Equipment, supplies, and medication. Equipment, supplies, and medication used in treating emergency cases are kept at the CAH and are readily available for treating emergency cases. The items available must include the following:	How does your facility ensure that the required equipment, supplies, and medications are always readily available in the CAH? Are they made available in accordance with State and local law? In accordance with accepted standards of practice?	Review of following document(s): □ Binder – CAH Emergency Department Policies and Procedures Inspection/tour of the Emergency Room Interviews with staff
C203	(1) <u>Drugs and biologicals</u> commonly used in life saving procedures, including analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarrythmics, cardiac glycosides, antihypertensives, diuretics, and electrolytes and replacement solutions.	Are appropriate drugs and biologicals available to the staff at all times? Is an inventory maintained? Do all hospital staff know how to access required drugs and biologicals 24 hours a day? See also NAC 449.343	Review of following document(s): □ Binder – CAH Emergency Department Policies and Procedures Inspection/tour of the Emergency Room Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C204	(2) Equipment and supplies commonly used in life saving procedures, including airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquet, immobilization devices, nasogastric tubes, splints, IV therapy supplies, suction machine, defibrillator, cardiac monitor, chest tubes, and indwelling urinary catheters.	Are equipment and supplies required at §485.618(b)(2) readily available? Does the staff know where emergency equipment and supplies are kept? Who is responsible for monitoring supplies? How are supplies replaced? When was the last time emergency supplies were used? Is there an equipment maintenance schedule, (e.g., for the defibrillator)? Are pediatric equipment and supplies available? Sterilized equipment will be examined. Functional capabilities of the oxygen supply systems will be assessed. The operating condition of the vacuum (suction) equipment will be checked.	Review of following document(s): Binder – CAH Emergency Department Policies and Procedures Equipment maintenance schedules Inspection/tour of the Emergency Room Interviews with staff
C205	(c) Standard: Blood and blood products. The facility provides, either directly or under arrangements, the following — (1) Services for the procurement, safekeeping and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hour-a-day basis.	This requirement can be met at a CAH by providing blood or blood products on an emergency basis at the CAH, either directly or through arrangement, if that is what the patient's condition requires. There is no requirement in the regulation for a CAH to store blood on site, although it may choose to do so. In some cases, it may be more practical to transport a patient to the source of the blood supply than to bring blood to the patient at the CAH. A facility that has the capability of providing blood services on site would be in compliance even if, in virtually all cases, the patients were actually taken to the blood rather than vice versa. A CAH that performs CLIA tests on blood on site must have a CLIA certificate and is subject to survey under CLIA. A CAH that is only storing blood for transfusion and refers all related testing out to another laboratory, is not performing testing as defined by CLIA. However, under this regulation, the CAH must ensure that blood is appropriately stored to prevent deterioration, including documenting refrigerator temperatures. The provision of blood services between the CAH and the testing laboratory should be reflected in the written agreement or arrangement between the two. Also, if the CAH is collecting blood, it must register with the Food and Drug Administration.	Review of following document(s): Binder – CAH Emergency Department Policies and Procedures Binder – CAH Laboratory Department Policies and Procedures Binder – CAH Agreements and Contracts – esp., a signed agreement with pathologist and it details his/her responsibilities. Refrigerator temperature logs Inspection/tour of the Emergency Room Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C205 continued	(c) Standard: Blood and blood products. The facility provides, either directly or under arrangements, the following – (1) Services for the procurement, safekeeping and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hour-a-day basis.	"Availability" in this context, means that the blood and blood products must be accessible to CAH staff in time to effectively treat emergency patients at the CAH. In order to comply with this requirement, a CAH must demonstrate that it has the capability (i.e., an effective system is in place regardless of whether, in actual practice, it has been utilized) of making blood products available to its emergency patients 24 hours a day. If a CAH performs type and compatibility testing it must have the necessary equipment, (i.e., serofuge and heat block), as well as typing and cross matching reagents, some of which have a 30-day expiration date. Another way for a CAH to meet this requirement would be to properly store 4 units of O negative packed red blood cells (the universal donor type) for availability at all times for emergencies only. CAHs that choose to store O negative packed red blood cells for emergency release of uncross matched blood will require a release form to be signed by a doctor, prior to transfusion, acknowledging that the blood has not been cross matched for the patient. Facilities that elect to store units of O negative packed red blood cells should be able to demonstrate that they have an arrangement (e.g., with the Red Cross or other similar product provider) for the provision of fresh units of O negative packed red blood cells. See sample policy C205 See also NAC 449.373, NAC 449.3735	Review of following document(s): Binder - CAH Emergency Department Policies and Procedures Binder - CAH Laboratory Department Policies and Procedures Binder - CAH Agreements and Contracts - esp., a signed agreement with pathologist and it details his/her responsibilities. Refrigerator temperature logs Inspection/tour of the Emergency Room Interviews with staff
C206	(2) Blood storage facilities that meet the requirements of 42 CFR part 493, Subpart K, and are under the control and supervision of a pathologist or other qualified doctor of medicine or osteopathy. If blood banking services are provided under an arrangement, the arrangement is approved by the facility's medical staff and by the person directly responsible for the operation of the facility.	If blood banking services are provided on-site, what evidence shows that the blood facility is under control and supervision of a pathologist or other qualified doctor of medicine or osteopathy? For blood banking services provided under arrangement, what evidence shows that the CAH medical staff and the person responsible for CAH operations have approved the arrangement?	Review of following document(s): Binder – CAH Emergency Department Policies and Procedures Binder – CAH Laboratory Department Policies and Procedures Binder – CAH Agreements and Contracts – esp., a signed agreement with pathologist and it details his/her responsibilities. Inspection/tour of the Emergency Room Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C207	(d) Standard: Personnel (1) Except as specified in paragraph (d) (2) in this section, there must be a doctor of medicine or osteopathy, a physician assistant, or a nurse practitioner with training or experience in emergency care on-call and immediately available by telephone or radio contact, and available onsite (i) within 30 minutes on a 24-hour-a-day basis, if the CAH is located in an area other than an area described in paragraph (d)(1)(ii) of this section or — (ii) within 60 minutes, if all of the following requirements are met: (A) the CAH is located in an area designated as a frontier area (i.e., an area with fewer than six residents per square mile based on the latest population data published by the Bureau of Censes); (B) the State has determined under criteria in its rural health care plan, that allowing an emergency response time longer than 30 minutes is the only feasible method of providing care to residents of the area served by the CAH; and (C) the State maintains documentation showing that the response time of up to 60 minutes at a particular CAH it designates is justified because other available alternatives would increase the time needed to stabilize a patient in an emergency. (2) A registered nurse satisfies the personnel requirement specified in paragraph (d)(1) of this section for a temporary period if — (i) the CAH has no greater than 10 beds; (ii) the CAH is located in an area designated as a frontier area or remote location as described in paragraph (d)(ii)(1) of this section. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of emergency services in the State. The letter from the Governor must also describe the circumstances and duration of the temporary request to include the registered nurses on the list of personnel specified in paragraph (d)(2))(ii) of this section, a CAH must submit documentation to the State survey agency demonstrating that it has been unable, due to	How does staff ensure that a doctor of mid-level provider is on call 24-hours-a-day and available on-site at the CAH within 30 minutes? Could any staff person at any time determine who the on-call person is? Is there evidence from documentation reviews that the 30 minute on-call requirement has been met? Expect the surveyors to show up at the hospital at any hour of the day to test this requirement! The person at the hospital makes the determination as to whether or not practitioner must come in. The "on call" practitioner does not. Note: Any exceptions to this standard must be submitted in writing to the Nevada FLEX Program, the Bureau of Licensure and Certification, and documented with the Nevada Office of Rural Health. The Nevada Rural Health Plan does not currently provide any exception to this standard. See sample policy C207 See also NAC 449.358, NAC 449.363	Review of following document(s): Binder - CAH Emergency Department Policies and Procedures Binder - CAH Agreements and Contracts Credentials files ER log ER oOn-call schedules Interviews with staff, patients, and families and/or observations as applicable Interviews with local officials (e.g., local volunteer rescue services, 911 dispatch services, local government, etc) to determine if there have been any instances when a properly trained or experienced CAH practitioner has not been available by telephone or at the CAH within 30 minutes

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C207 continued	in the area, to provide adequate coverage as specified in this paragraph (d). (3) The request, as specified in paragraph (d)(2)(ii) of this section, and the withdrawal of the request, may be submitted to CMS at any time, and are effective upon submission.		
C209	(e) Standard: Coordination with emergency response systems. The CAH must, in coordination with emergency response systems in the area, establish procedures under which a doctor of medicine or osteopathy is immediately available by telephone or radio contact on a 24-hour-aday basis to receive emergency calls, provide information on treatment of emergency patients, and refer patients to the CAH or other appropriate locations for treatment.	The hospital has in place a system to immediately put a doctor of medicine or osteopathy in communication with emergency responders. Note: This is a requirement for the hospital, not the ambulance service or local emergency response system. This requirement contemplates that the doctor from his residence or from someplace outside the hospital could make this contact as well as from the hospital What records will demonstrate that the procedures are followed and evaluated? See sample policy C209 and sample agreement C194	Review of following document(s): □ Binder – CAH Emergency Department Policies and Procedures □ Binder – CAH Agreements and Contracts □ ER log Interviews with staff
C210	§485.620 Condition of participation: Number of beds and length of stay.		Pre-survey research & compliance previously determined by the Nevada Office of Rural Health via your hospital's completion of the "Preliminary Application for Eligibility Determination."
C211	(a) Standard: Number of beds. Except as permitted for CAHs having distinct part units under §485.645 of this chapter, the CAH maintains no more than 25 inpatient beds that can be used for either inpatient or swing-bed services.	All hospital-type beds located in the CAH will be counted to establish the number of beds regardless of admission status. The CAH may not have more than 25 beds that could be used for inpatient care. Any hospital-type bed located in or adjacent to any location where the bed could be used for inpatient care counts toward the 25 bed limit. Beds that do not count toward the 25 bed limit are: (a) examination or procedure tables; (b) stretchers; (c) operating room tables located in the operating room and used exclusively to conduct surgery on a patient; (d) beds in a surgical recovery room that are used exclusively for surgical patients during recovery from anesthesia; (e) beds in an obstetric delivery room that are used exclusively for observation of OB patients in active	Review of following document(s): Review of open and closed medical records Facility inspection and bed count Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C211 continued	(a) Standard: Number of beds. Except as permitted for CAHs having distinct part units under §485.645 of this chapter, the CAH maintains no more than 25 inpatient beds that can be used for either inpatient or swing-bed services.	labor and delivery of newborn infants (do count beds in birthing rooms where the patient remains after giving birth); (f) newborn bassinets and isolettes used for well baby boarders; (g) stretchers in emergency departments; and (h) beds in Medicare certified distinct part rehabilitation or psychiatric units. Observation Patient Services — Observation services are defined as services furnished by a CAH to evaluate an outpatient's condition to determine the need for discharge or possible admission as an inpatient. The maximum stay in observation status is 48 hours. If the stay needs to be extended, the patient should be admitted or transferred, as appropriate. The stays must always be medically necessary (not for MD/DO or patient convenience). An MD/DO order is required for observation status. Samples of appropriate use of observation status include: (a) following an ER visit to ensure the patient is stable; (b) following outpatient medical procedures; (c) following minor surgery; or (d) chest pain workup, asthma, or congestive heart failure treatments. The beneficiary may not be aware that observation stays fall under Part B and require coinsurance and possibly other CAH charges. The CAH must give written notice of noncoverage to the beneficiary (ABN) prior to the stay. Beds, used by patients on observation status, that conform to the hospital-type beds previously discussed in this requirement, will be counted as part of the maximum bed count.	Review of following document(s): Review of open and closed medical records Facility inspection and bed count Interviews with staff
		Counting Hospice Patients in a CAH — A CAH can dedicate beds to a hospice under arrangement but the beds must count as part of the maximum bed count. The computation contributing to the 96 hour annual average length of stay does not apply to hospice patients. The hospice patient can be admitted to the CAH for any care involved in their hospice treatment plan or for respite care. Medicare does not reimburse the CAH for the hospice CAH benefit. Medicare reimburses the hospice. The CAH must negotiate payment for services from the hospice through an agreement.	

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C212	(b) Standard: Length of stay. The CAH provides acute inpatient care for a period that does not exceed, on an average annual basis, 96 hours per patient.	Note: The Fiscal Intermediary (FI) will determine compliance with this CoP. The FI will calculate the CAH's Medicare length of stay based on patient census data from the facility cost report data. If a CAH exceeds the length of stay limit for Medicare beneficiaries, the FI will extend their review to other patient care data obtained from the facility, such as medical records, to calculate the facility average. If the FI still finds the facility average patient length of stay in excess of 96 hours, the FI will send a report to the CMS-RO as well as a copy of the report to the SA. The CAH will be required to develop and implement a plan of correction (POC) acceptable to the CMS Regional Office or provide adequate information to demonstrate compliance.	Review of following document(s): Binder – CAH Policies and Procedures Current monthly log of inpatient length of stay Utilization review reports
C220	§485.623 Condition of Participation: Physical Plant and Environment.	This COP applies to all locations of the CAH, all campuses, all satellites, all provider-based activities, and all inpatient and outpatient locations. Most of the standards under this COP remain the same. The CAH's departments or services responsible for the CAH's building and equipment maintenance (both facility equipment and patient care equipment) must be incorporated into the CAH' QA program and be in compliance with the QA requirements. CAHs must meet the provisions of the 2000 Life Safety Code of the National Fire Protection Association. Hospitals are no longer grandfathered in under the 1967 provisions. CMS may waive specific provisions of the 2000 Life Safety Code if proven they would result in unreasonable hardship for the CAH, but not adversely affect patients. Such requests must be made by the state. See also NAC 449.3154-5, NAC 449.316	Review of following document(s): □ Binder – CAH Maintenance/Physical Plant Policies and Procedures Facility inspection Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C221	(a) <u>Standard: Construction</u> . The CAH is constructed, arranged, and maintained to ensure access to and safety of patients and provides adequate space in the provision of direct services.	Physical facilities must be large enough, numerous enough, appropriately designed and equipped, and of appropriate complexity to provide the services offered in accordance with Federal and State laws, regulations and guidelines and accepted standards of practice for that location or service. During the tour of the facility, surveyors will observe your facility to determine and ensure that this condition is met. See also NAC 449.3154, NAC 449.3156, NAC 449.316	Facility inspection to observe direct serve areas for adequate space to ensure patient safety and to facilitate the provision of direct services (i.e., patient examination and treatment areas, laboratory, radiology, and emergency services) Interviews with staff
C222	(b) Standard: Maintenance. The CAH has housekeeping and preventive maintenance programs to ensure that: (1) All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition;	The CAH must ensure that the condition of the physical plant and overall CAH environment is developed and maintained in a manner to ensure the safety and well being of patients. This includes ensuring that routine and preventive maintenance and testing activities are performed as necessary, in accordance with Federal and State laws, regulations, and guidelines and manufacturer's recommendations, by establishing maintenance schedules and conducting ongoing maintenance inspections to identify areas or equipment in need of repair. The routine and preventive maintenance and testing activities should be incorporated into the CAH's QA plan. Facilities must be maintained to ensure an acceptable level of safety and quality. Supplies must be maintained to ensure an acceptable level of safety and quality. Equipment must be maintained to ensure an acceptable level of safety and quality. Equipment includes both facility equipment (e.g., elevators, generators, air handlers, medical gas systems, air compressors and vacuum systems, etc.) and medical equipment (e.g., biomedical equipment, radiological equipment, patient beds, stretchers, IV infusion equipment, ventilators, laboratory equipment, etc.).	Review of following document(s): Binder – CAH Maintenance/Physical Plant Policies and Procedures Routine and preventive maintenance schedules Maintenance records and logs Facility inspection Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C222 continued	(b) Standard: Maintenance. The CAH has housekeeping and preventive maintenance programs to ensure that: (1) All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition;	There must be a regular periodical maintenance and testing program for medical devices and equipment. A qualified individual such as a clinical or biomedical engineer, or other qualified maintenance person, must monitor, test, calibrate and maintain the equipment periodically in accordance with the manufacturer's recommendations and Federal and State laws and regulations. Equipment maintenance may be conducted using CAH staff, contracts, or through a combination of CAH staff and contracted services. See also NAC 449.316	Review of following document(s): □ Binder – CAH Maintenance/Physical Plant Policies and Procedures □ Routine and preventive maintenance schedules □ Maintenance records and logs Facility inspection Interviews with staff
C223	(2) There is proper routine storage and prompt disposal of trash;	Is trash, including biohazardous waste, contaminated materials, stored and disposed of promptly and properly? Does the storage and disposal of trash conform with state licensure regulations, as well as Federal, State, and local laws and regulations (e.g., EPA, OSHA, CDC regulations)?	Review of following document(s): □ Binder – CAH Maintenance/Physical Plant Policies and Procedures □ Maintenance records Facility inspection – inside and out Interviews with staff
C224	(3) Drugs and biologicals are appropriately stored;	What standards or guidelines does your facility follow to ensure that drugs and biologicals are appropriately stored (e.g., esp., "locked")? See also NAC 449.373	Review of following document(s): □ Binder – CAH Maintenance/Physical Plant Policies and Procedures □ Binder – CAH Pharmacy Department Policies and Procedures Facility inspection Interviews with staff
C225	(4) The premises are clean and orderly; and	This is a self-explanatory, yet essential issue that must be addressed prior to the certification survey. "Clean and orderly" means an uncluttered physical environment where patients and staff can function safely (e.g., equipment and supplies stored in proper spaces, not in corridors, spills not left unattended or identified, no floor obstructions). "Clean and orderly" also means that the facility is neat and well kept (e.g., no peeling paint, visible water leaks, plumbing problems).	Facility inspection Interviews with Staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C226	(5) There is proper ventilation, lighting, and temperature control in all pharmaceutical, patient care, and food preparation areas.	Temperature, humidity and airflow in the operating rooms must be maintained within acceptable standards to inhibit bacterial growth and prevent infection, and promote patient comfort. Excessive humidity in the operating room is conducive to bacterial growth and compromises the integrity of wrapped sterile instruments and supplies. Each operating room should have separate temperature control. Acceptable standards such as from the Association of Operating Room Nurses (AORN) or the American Institute of Architects (AIA) should be incorporated into CAH policy. The CAH must ensure that an appropriate number of refrigerators and/or heating devices are provided and ensure that food and pharmaceuticals are stored properly and in accordance with nationally accepted guidelines (food) and manufacturer's recommendations (pharmaceuticals).	Review of following document(s): Binder – CAH Maintenance/Physical Plant Policies and Procedures Maintenance records Facility inspection, including inspection of food storage and preparation areas, pharmaceutical storage areas, and operating room environment Interviews with staff
C227	(c) Standard: Emergency procedures. The CAH assures the safety of patients in non-medical emergencies by – (1) Training staff in handling emergencies, including prompt reporting of fires, extinguishing of fires, protection and where necessary, evacuation of patients, personnel, and guests, and cooperation with fire fighting and disaster authorities;	Are fire and emergency drills conducted regularly? Do all staff know what they are supposed to do in case of an emergency such as a tornado or a blizzard? See also NAC 449.316	Review of following document(s): Binder – CAH Maintenance/Physical Plant Policies and Procedures Binder – CAH Fire Safety Plan Binder – CAH Disaster Plan Binder – CAH Bioterrorism Preparedeness Plan Staff training and inservice records (to validate training) Facility inspection Interviews with and disaster scenarios posed to entire clinical and non-clinical staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C228	(2) Providing for emergency power and lighting in the emergency room and for battery lamps and flashlights in other areas;	The CAH must comply with the applicable provisions of the Life Safety Code, National Fire Protection Amendments (NFPA) 101®, 2000 Edition and applicable references such as NFPA-99®: Health Care Facilities, for emergency lighting and emergency power. Does the emergency generator have adequate capacity to provide power for emergency equipment and lighting in the emergency room? Are there maintenance records and facility specific policies and procedures or test runs and frequency of test runs on emergency equipment?	Review of following document(s): Facility completion of Life Safety Code Survey Report Form (CMS-2786) Binder - CAH Maintenance/Physical Plant Policies and Procedures Binder - CAH Fire Safety Plan Binder - CAH Disaster Plan Maintenance records documenting test runs and frequence of test runs Facility inspection Interviews with staff
C229	(3) Providing for an emergency fuel and water supply; and	The CAH must have a system to provide emergency gas and water as needed to provide care to inpatients and other persons who may come to the CAH in need of care. This includes making arrangements with local utility companies and others for the provision of emergency sources of water and gas. The CAH should consider nationally accepted references or calculations made by qualified staff when determining the need for water and gas. For example, one source for information on water is the Federal Emergency Management Agency (FEMA). Emergency gases include fuels such as propane, natural gas, fuel oil, liquefied natural gas, as well as any gases the CAH uses in the care of patients such as oxygen, nitrogen, nitrous oxide, etc. The CAH should have a plan to protect these limited emergency supplies, and have a plan for prioritizing their use until adequate supplies are available. The plan should also address the event of a disruption in supply (e.g., disruption to the entire surrounding community). What arrangements have been made for fuel and water in the event normal sources are degraded? If hospital is heated with oil, be prepared to have a signed agreement from supplier that hospital will be considered "priority" customer in emergencies or shortage situations.	Review of following document(s): Binder - CAH Maintenance/Physical Plant Policies and Procedures Binder - CAH Fire Safety Plan Binder - CAH Disaster Plan Binder - CAH Agreements and Contracts Facility inspection Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C230	(4) Taking other appropriate measures that are consistent with the particular conditions of the area in which the CAH is located.	Note: The CAH must develop and implement a comprehensive plan to ensure that the safety and well being of patients are assured during emergency situations. Assuring the safety and well being of patients would include developing and implementing appropriate emergency preparedness plans and capabilities. The CAH must coordinate with Federal, State, and local emergency preparedness and health authorities to identify likely risks for their area (e.g., natural disasters, bioterrorism threats, disruption of utilities such as water, sewer, electrical communications, fuel; nuclear accidents, industrial accidents, and other likely mass casualties, etc.) and to develop appropriate responses that will ensure the safety and well being of patients. Does the facility have policies and procedures in place that address the specific conditions for the area in which the CAH is located (e.g., snowbound facility, spring flooding)?	Review of following document(s): Binder – CAH Maintenance/Physical Plant Policies and Procedures Binder – CAH Fire Safety Plan Binder – CAH Disaster Plan Facility inspection Interviews with staff
C231	(d) Standard: Life safety from fire. (1) Except as provided in this section, the CAH must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101 2000 edition of the LSC, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. A copy of the Code is available for inspection at the CCMS Information Resource Center, 7500 Security Boulevard, Baltimore MD and at the Office of the Federal Register, 800 North Capital Street NW Suite 700, Washington DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes. Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the Life Safety Code does not apply to a CAH.	It is presumed that your facility is currently meeting life safety requirements – check to see that this is the case. CAH life safety codes (Tags C231-234) are no more demanding than current requirements. This revision adopts the 2000 edition of the LSC and deletes provisions for the use of roller latches in the facility. The entire building occupied by the CAH will be surveyed unless there is a 2-hour firewall separating the spaced designated as the CAH from the remainder of the building. A 2-hour floor slab does not count; it must be a vertical firewall to constitute a separate building or part of a building.	Review of following document(s): □ Facility completion of form (CMS-2786) used by the Fire Authority surveyor to evaluate compliance with the Life Safety Code and a separate 1985 Life Safety Code Addendum to be used when surveying for compliance with the 1985 Life Safety Code. Inspection of the entire facility Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C232	(2) If CMS finds that the State has a fire and safety code imposed by State law that adequately protects patients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the LSC.	This revision deletes "grandfathering" of older editions of the LSC and allows the use of a State code if approved by CMS.	Facility inspection Interviews with staff
C233	(3) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the CAH, but only if the waiver does not adversely affect the health and safety of patients.	If available, waiver will be reviewed.	Facility inspection Interviews with staff
C234	(4) The CAH maintains written evidence of regular inspection and approval by State and local fire control agencies.		Review of following document(s): Inspection and approval reports from State and local fire control agencies.
C235	(5) A CAH must be in compliance with the following provisions beginning on March 13, 2006 – (i) Chapter 19.3.6.3.2 exception number 2 (ii) Chapter 19.2.9 Emergency Lighting.	§485.623(d)(1) states, "Chapter 19.3.6.3.2 exception number 2 of the adopted edition of the Life Safety Code does not apply to CAH." The wording in §485.623(d)(5) and §485.623(d)(5)(i) when used together means that after March 13, 2006, a CAH may no longer continue to keep in service existing roller latches even when these roller latches have been demonstrating the ability to keep the door closed against 5lbf. Beginning March 13, 2006, Medicare-participating CAHs must be in compliance with chapter 19.3.6.3.2 of the 2000 Edition of NFPA 101®. Beginning March 13, 2006, exception number 2 of chapter 19.3.6.3.2 will not be allowed in Medicare-participating CAHs. CAHs should develop plans for compliance with this requirement so that in all applicable locations roller latches have been replaced by positive latches prior to March 13, 2006. Beginning March 13, 2006, Medicare-participating CAHs must be in compliance with Chapter 19.2.9 of the 2000 Edition of NFPA 101®. This section gives facilities until March 13, 2006, to replace roller latches and to replace 1 hour batteries with 1-1/2 hour batteries in emergency lighting systems that use batteries as power sources. After March 13, 2006, a CAH with doors in service with roller latches or with emergency lighting systems with less than 1-1/2 hour batteries will not be in compliance and will be cited at 485.623(d)(1).	Facility inspection

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C240	§485.627 Condition of participation: Organizational Structure	there must be written documentation that identifies the indiction that the CAH operations. The governing body (or responsible in which categories of practitioners are eligible candidates for the governing body (or responsible individual) to appoint, or practitioners to the medical staff. After considering medical CAH medical staff criteria and State and Federal laws and a decides whether or not to appoint new medical staff member. The governing body (or responsible individual) must ensure Federal law and the requirements of the CAH CoP. The governot to approve medical staff bylaws submitted by the medical approved by the governing body (or responsible individual) (or responsible individual) must ensure that the medical staff individual) for the quality of care provided to patients. The for the conduct of the CAH and this conduct would include must be under the care of a member of the medical staff or of a member of the medical staff. All patient care is provided granted privileges to provide or order that care and is in accordance.	institution. In the absence of an organized governing body, vidual or individuals that are responsible for the conduct of adividual) must determine, in accordance with State law, appointment to the medical staff. It is the responsibility of with the advice of the medical staff, the individual all staff recommendations, and in accordance with established regulations, the governing body (or responsible individual) errs or to continue current members of the medical staff. The medical staff has bylaws that comply with State and verning body (or responsible individual) decides whether or all staff. The medical staff bylaws and any revisions must be a before they are considered effective. The governing body ff is accountable to the governing body (or responsible at the quality of care provided to patients. All CAH patients under the care of a practitioner who is under the supervision ed by or in accordance with the orders of a practitioner cordance with State law. Criteria for selection of both new if members for continued membership must be based on the
C241	(a) Standard: Governing body or responsible individual. The CAH has a governing body or an individual that assumes full legal responsibility for determining, implementing and monitoring policies governing the CAH's total operation and for ensuring that those policies are administered so as to provide quality health care in a safe environment.	Have the facility's operating policies been updated to fully reflect its responsibilities as a CAH (e.g., responsibilities of mid-level providers, provision of required direct CAH services)? Is there evidence that the governing body is fully responsible for the operations? For initial surveys, is there evidence that the governing body has approved the effort to become a CAH? These assurances are probably contained in board meeting minutes and/or general facility policies and procedures.	Review of following document(s): CAH Organizational Chart Binder – CAH Governing Board By Laws CAH Governing Body meeting agenda and minutes Binder – CAH Job Descriptions Form CMS-855 – to determine if there are any inconsistencies relative to demonstrated evidence of actual CAH operations Facility inspection Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C242	 (b) <u>Standard: Disclosure</u>. The CAH discloses the names and addresses of – (1) Its owners, or those with a controlling interest in the CAH or in any subcontractor in which the CAH directly or indirectly has a 5 percent or more ownership interest, in accordance with Subpart C of part 420 of this chapter; 	Have ownership and address lists been updated to indicate that the administration and ownership of a CAH, per se? What are the CAH's policies for reporting change of ownership to the State?	Review of following document(s): CAH Organizational Chart Binder – CAH Governing Board By Laws Binder – CAH Job Descriptions
C243	(2) The person principally responsible for the operation of the CAH; and	This individual is typically the hospital administrator and/or CEO. The surveyors will simply want evidence that the "CAH Administrator" is the person principally responsible for the operation of the CAH and that responsibility has been approved by the hospital board. What are the CAH's policies for reporting change of CAH administrators to the State?	Review of following document(s): CAH Organizational Chart Binder – CAH Governing Board By Laws Binder – CAH Job Descriptions
C244	(3) The person responsible for medical direction.	Is there a designated medical director for the hospital? Are the duties and responsibilities of the medical director clearly spelled out. What are the CAH's policies for reporting change of medical staff direction to the State? See also NAC 449.355	Review of following document(s): CAH Organizational Chart Binder – CAH Governing Board By Laws Binder – CAH Medical Staff By Laws Binder – CAH Job Descriptions
C250	§485.631 Condition of participation: Staffing and staff responsibilities		
C251	(a) Standard: Staffing. (1) The CAH has a professional health care staff that includes one or more doctors of medicine or osteopathy and may include one or more physician assistants, nurse practitioners, or clinical nurse specialists.	A CAH may operate with all MD/DOs on staff as well as with any combination of mid-level practitioners and physicians. Is there either a doctor of medicine or osteopathy on staff with a PA, NP or CNS? Is there an organizational chart, showing staff physicians, mid-levels and nursing staff? If so, provide or prepare current documentation. See also NAC 449.358, NAC 449.361	Review of following document(s): CAH Organizational Chart CAH work schedules during normal CAH hours of operation Facility inspection Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C252	(2) Any ancillary personnel are supervised by the professional staff.	All ancillary personnel are supervised by the professional staff. Have organizational charts been kept current? If not, have an up-date (and date) organizational chart.	Review of following document(s): CAH Organizational Chart Interviews with staff
C253	(3) The staff is sufficient to provide the services essential to the operation of the CAH.	Staff coverage is sufficient to provide essential services at the facility (e.g., emergency services described at §485.618, direct services described at §485.635(b), and nursing services described at §485.631(d)? Are staffing records and census records compatible?	Review of following document(s): Current staff schedules Daily census records Interviews with staff
C254	(4) A doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist or physician assistant is available to furnish patient care services at all times the CAH operates.	Section 485.635(b)(1) requires CAHs to provide "those diagnostic and therapeutic services and supplies that are commonly furnished in "a physicians office" such as low intensity outpatient services. In order to demonstrate compliance, a CAH must demonstrate that a practitioner is physically present and prepared to treat patients at the CAH when patients present at the CAH outpatient clinic during announced hours of outpatient clinic operation. This requirement does not mean the CAH must have a practitioner physically present in the facility 24 hours per day, nor does it require their presence 24 hours per day when the CAH has inpatients, including swing-bed patients. If the hospital operates outpatient clinics, a doctor of medicine or osteopathy, PA, NP, or CNS is physically present and prepared to treat patients. Outpatient clinics have specific, posted operating hours. You cannot staff a clinic with a receptionist whose job it is to call a practitioner to come in when a patient shows up	Review of following document(s): Current staff schedules Daily census records Interviews with staff
C255	(5) A registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the CAH has one or more inpatients.	Note: If a nurse practitioner is on duty in the CAH, both requirements at §485.631(a)(4) and (5) are met. However, if a physician assistant is on duty, §485.631 (a)(4) is met, but §485.631(a)(5) is not met unless a registered nurse, clinical nurse specialist or licensed practical nurse is also on duty. See sample policy C255	Review of following document(s): Current nurse staff schedules Daily census records Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C256	(b) Standard: Responsibilities of the doctor of medicine or osteopathy. (1) The doctor of medicine or osteopathy –	See also NAC 449.358	Review of following document(s): CAH Organizational Chart Binder – CAH Medical Staff By Laws Credential files for physicians and mid-level providers Binder – CAH Agreements and Contracts Interviews with staff
C257	(i) Provides medical direction for the CAH's health care activities and consultation for the medical supervision of the health care staff;	A CAH must have a MD/DO on its staff. That individual must perform all of the medical oversight functions. Surveyors will be looking for evidence that demonstrates that the doctor of medicine or osteopathy provides medical direction for the CAH's healthcare activities and is available for consultation and supervision of the CAH health care staff.	Review of following document(s): CAH Organizational Chart Binder – CAH Medical Staff By Laws Credential files for physicians and mid-level providers Binder – CAH Agreements and Contracts Interviews with medical staff and medical staff director
C258	(ii) In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the CAH's written policies governing the services it furnishes.	Does a doctor of medicine or osteopathy participate in the development of policies governing services? Are these policies periodically reviewed by the doctor of medicine or osteopathy? See sample policy C258	Review of following document(s): CAH Organizational Chart Binder – CAH Governing Board By Laws Binder – CAH Medical Staff By Laws Interviews with staff
C259	(iii) In conjunction with the physician assistant and/or nurse practitioner member(s), periodically reviews the CAH's patient records, provides medical orders, and provides medical care services to the patients of the CAH; and	Does the doctor of medicine or osteopathy periodically review patient records in conjunction with staff mid-level practitioners? Is there evidence of a periodic review of patient records by the CAH physician? See sample policy C259	Review of following document(s): CAH Organizational Chart Binder – CAH Medical Staff By Laws and any periodic review policies and procedures Review of open and closed medical records Interviews with medical staff and nursing staff
C260	(iv) Periodically reviews and signs the records of patients cared for by nurse practitioners, clinical nurse specialists, or physician assistants.	Note: The CAH physician must review and sign all inpatient records for patients cared for by mid-level practitioners. The CAH physician is not required to review and sign all outpatient records for patients cared for by mid-level practitioners. What is the CAH policy regarding periodic reviews?	Review of following document(s): CAH Organizational Chart Binder – CAH Medical Staff By Laws and any periodic review policies and procedures Review of open and closed medical records Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C261	(2) A doctor of medicine or osteopathy is present for sufficient periods of time, at least once in every two week period (except in extraordinary circumstances) to provide the medical direction, medical care services, consultation, and supervision described in this paragraph, and is available through direct radio or telephone communication for consultation, assistance with medical emergencies, or patient referral. The extraordinary circumstances are documented in the records of the CAH. A site visit is not required if no patients have been treated since the last site visit.	Is there evidenced of a doctor of medicine or osteopathy's provision of medical direction, medical care services, consultation, and supervision? How does the CAH ensure that the physician is available by telephone or radio contact for consultation, assistance, and/or patient referral?	Review of following document(s): CAH Organizational Chart Binder – CAH Medical Staff By Laws Binder – CAH Agreements and Contracts Interviews with staff
C262	(c) Standard: Physician assistant, nurse practitioner, and clinical nurse specialist responsibilities. (1) The physician assistant, the nurse practitioner, or clinical nurse specialist members of the CAH's staff –		Review of following document(s): Meeting minutes and agenda – CAH Policies and Procedures Committee Interviews with staff, including NPs, CNSs, and/or PAs
C263	(i) Participate in the development, execution and periodic review of the written policies governing the services the CAH furnishes; and	Mid-level providers will be interviewed to assess the extent to which NPs, CNSs, and/or PAs are involved in the policy development, execution, and periodic review? Are policies updated regularly? Are CAH policies for mid-levels consistent with Nevada standards of practice and requirements for NPs, CNSs, and/or PAs?	Review of following document(s): Meeting minutes and agenda – CAH Policies and Procedures Committee Interviews with NPs, CNSs, and/or PAs
C264	(ii) Participate with a doctor of medicine or osteopathy in a periodic review of the patient's health records.	Do PAs, NPs, and/or CNSs participate with a doctor of medicine or osteopathy in the review of their patients' health records?	Review of following document(s): Review of open and closed medical records Interviews with NPs, CNSs, and/or PAs
C265	(2) The physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathy: (i) Provides services in accordance with the CAH's policies; and	Are all mid-levels knowledgeable regarding the hospitals policies and procedures? Do they understand the unique status of CAH?	Review of following document(s): □ Review of open and closed medical records Interviews with NPs, CNSs, and/or PAs

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C267	(ii) Arranges for, or refers patients to, needed services that cannot be furnished at the CAH and assures that adequate patient health records are maintained and transferred as required when patients are referred.	Are there referral arrangements in place with higher level facilities, particularly with reference to OB, cardiac and trauma? Are all staff aware of referral agreements? Are all staff aware of EMTALA requirements? Are there policies that address transfer of records when patient is transferred? See sample policy C267 See sample transfer agreement	Review of following document(s): Review of open and closed medical records Binder - CAH Agreements and Contracts - esp., transfer agreements Interviews with staff
C268	(3) Whenever a patient is admitted to the CAH by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or osteopathy on the staff of the CAH is notified of the admission.	The CAH regulations do permit licensed mid-level practitioners, as allowed by the State, to admit patients to a CAH. However, CMS regulations do require that Medicare and Medicaid patients be under the care of an MD/DO if admitted by a mid-level practitioner and the patient has any medical or psychiatric problem that is present on admission or develops during hospitalization that is outside the scope of practice of the admitting practitioner. Evidence of being under the care of an MD/DO must be in the patient's medical record. If a CAH allows a mid-level practitioner to admit and care for patients, as allowed by State law, the governing body (or responsible individual) and medical staff would have to establish policies and bylaws to ensure patient safety. As applicable, the patient's medical record must demonstrate MD/DO responsibility/care. Does a policy require notification of a doctor of medicine or osteopathy when inpatients are admitted? Does your facility have a documented system of notification in place? See sample policy C268	Review of following document(s): List of admitting privileges CAH Medical Staff By-Laws Review of open and closed medical records Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C270	§485.635 Condition of participation: Provision of services.	See also NAC 449.331 – 449.394	
C271	 (a) Standard: Patient care policies. (1) The CAH's health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law. 	Would observance of staff in daily duties support adherence to policies and procedures. Do they reflect current thinking/literature in procedures? Are all of the regulatory required policies and procedures in place? What evidence indicates that patients are receiving care in accordance with written policies for health care services consistent with Nevada law?	Review of following document(s): Binder – CAH Patient Services Policies and Procedures Review of open and closed medical records Facility inspection and observation of staff delivering health care services to patients Interviews with staff
C272	(2) The policies are developed with the advice of a group of professional personnel that includes one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of §485.631(a)(1); at least one member is not a member of the CAH staff.	A CAH with a full time MD/DO is not required to have a mid-level practitioner on staff and would not have to obtain the services of a mid-level practitioner on a contractual or voluntary basis to participate in writing the facility's health care services policies. The member of the group who is not a member of the CAH staff must be a licensed health care professional. Physician is involved in and approves all clinical policies. Policies and procedures have been approved by a committee composed of clinical staff of CAH and at least one non-staff professional.	Review of following document(s): Binder – CAH Patient Services Policies and Procedures Meeting minutes and agenda – CAH Policies and Procedures Committee Review of open and closed medical records Facility inspection and observation of staff delivering health care services to patients Interviews with staff
C273	(3) The policies include the following: (i) A description of the services the CAH furnished directly and those furnished through agreement or arrangement.	Do policies clearly explain what type of health care services are available by staff, which are furnished through agreements or arrangements? Arrangements and/or agreements include services provided through formal contracts, joint ventures, informal agreements, or lease arrangements. Additional services furnished through referral should be clearly described in statements such as "arrangements have be made with hospital X for CAH patients to receive the following services x, y, z"	Review of following document(s): Meeting minutes and agenda – CAH Policies and Procedures Committee Binder – CAH Agreements and Contracts Facility inspection and observation of staff delivering health care services to patients Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C274	(ii) Policies and procedures for emergency medical services.	Policies should show how the CAH would meet all of its emergency services requirements Do policies show what emergency services requirements are provided by staff, by contract, by consultant, by transfer? Do policies define an "appropriate medical screening examination" and who can do it? See also NAC 449.349, NAC 449.331	Review of following document(s): Meeting minutes and agenda – CAH Policies and Procedures Committee Binder – CAH Agreements and Contracts Binder – Emergency Department Policies and Procedures Facility inspection and observation of staff delivering health care services to patients Interviews with staff
C275	(iii) Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the CAH.	Guidelines for the medical management of health problems should include a description of the scope of medical acts that may be performed by the mid-level practitioners. Guidelines represent an agreement between the MD/DO providing the CAH's medical direction and the CAH's mid-level practitioners relative to the privileges and limits of those acts of medical diagnosis and treatment that may be undertaken with direct MD/DO supervision. Guidelines should describe the regimens to follow and also stipulate the condition in the illness or health care management when consultation or referral is required. Regardless of the format used by the CAH for its medical management guidelines, they should include the following essential elements: (a) They should be comprehensive enough to cover most health problems	Review of following document(s): Binder – CAH Agreements and Contracts Binder – CAH Medical Records Policies and Procedures Binder – CAH Medical Staff By Laws and other guidelines for medical management Credential files for physicians and mid-level providers Interviews with staff, medical staff, and mid-level providers
		that patients usually refer to a physician; (b) They should describe the medical procedures available to the midlevels in the facility; (c) They should describe the medical conditions, signs, or developments that require consultation or referral; and (d) They should be compatible with Nevada law. Note: Surveyors will be looking for evidence that the CAH's guidelines for medical management of health problems accurately reflect the actual clinical capabilities of the facility and that medical guidelines are followed.	

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C276	(iv) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.	Pharmaceutical services must be administered in accordance with accepted professional principles. Accepted professional principles include compliance with applicable Federal and State laws, regulations, and guidelines governing pharmaceutical services, as well as, standards or recommendations promoted by nationally recognized professional organizations such as the American Society of Health-System Pharmacists (ASHP). A fundamental purpose of pharmaceutical services is to ensure the safe and appropriate use of medications and medication-related devices. The pharmacy director, with input from appropriate CAH staff and committees, develops, implements and periodically reviews and revises policies and procedures governing provision of pharmaceutical services. Methods a CAH uses to maintain professional principles include: (a) Policies and procedures have been developed and are being followed; (b) drugs and biologicals are stored in accordance with manufacturers directions and State and Federal requirements; (c) employees provide pharmaceutical services within their scope of license and education; (d) pharmacy records have sufficient detail to follow the flow of pharmaceuticals from their entry into the CAH through dispensation/administration; (f) the pharmacy maintains controls over drugs and medications in all CAH locations, including floor stock; (g) maintaining pharmacy and accounting records pertaining to the requisitioning and dispensing of drugs and pharmaceutical supplies; (h) ensuring that drugs are being dispensed only by a licensed pharmacist; and (i) only pharmacists or pharmacy-supervised personnel compound, label and dispense drugs or biologicals. Pharmaceutical services at a CAH can be provided either as direct services or through an agreement. The direction of pharmaceutical services may not require continuous on-premise supervision at the CAH's pharmacy but may be accomplished through regularly scheduled visits, and/or telemedicine in accordance with Federal and State law and regulation and accep	Review of following document(s): Binder – CAH Agreements and Contracts Review of open and closed medical records Facility inspection, including dispensation of drugs, drug labeling and expiration dates, and drug storage Interview with chief pharmacist and pharmacy staff Interviews with all clinical staff regarding familiarity with medication-related policies and procedures

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C276 continued	(iv) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.	A single pharmacist must be responsible for the overall administration of the pharmacy service whether employed by the CAH or obtained through agreement. The pharmacist must be responsible for developing, supervising, and coordinating all the activities of the CAH-wide pharmacy service and must be thoroughly knowledgeable about CAH pharmacy practice and management.	Review of following document(s): Binder – CAH Pharmacy Policies and Procedures Binder – CAH Agreements and Contracts Review of open and closed medical records Facility inspection, including dispensation of drugs, drug labeling and expiration dates, and drug storage
		The job description or the written agreement for the responsibilities of the pharmacist should be clearly defined and include development, supervision and coordination of all the activities of pharmacy services. Pharmacists and pharmacy technicians must perform their duties within the scope of their license and education. There must be sufficient personnel to respond to the pharmaceutical needs of the patient population being served. The pharmaceutical services staff must be sufficient in types, numbers, and training to provide quality services, including 24 hour, 7-day emergency coverage, or there may be an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff. There must be sufficient numbers and types of personnel to provide accurate and timely medication delivery, ensure accurate and safe medication administration and to provide appropriate clinical services as well as the participation in continuous quality improvement programs that meet the needs of the patient population being served. The CAH must have a system that ensures that medication orders get to the pharmacy and drugs get back to patients promptly.	Interview with chief pharmacist and pharmacy staff Interviews with all clinical staff regarding familiarity with medication-related policies and procedures

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C276 continued	(iv) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.	Record System Components of a record system to maintain current and accurate records of the receipt and disposition of scheduled drugs would include: (a) Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs; (b) records of the receipt and disposition of all scheduled drugs must be current and must be accurate; and (c) records trace the movement of scheduled drugs throughout the service. The pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled. The record system, delineated in policies and procedures, tracks movement of all scheduled drugs from the point of entry into the CAH to the point of departure either through administration to the patient, destruction of the drug, or return to the manufacturer. This system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs. The CAH system should be capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual losses or diversion to the time of detection and determination of the extent of loss or diversion. Facility policies and procedures should minimize scheduled drug diversion. Receipt and Distribution of Drugs Drugs and biologicals must be controlled and distributed in accordance with applicable Federal and State laws and regulations, and in accordance with applicable standards of practice include compliance with all Federal and State laws, regulations, and guidelines, as well as, standards and recommendations promoted by nationally recognized professional organizations, that apply to pharmaceutical safety and the control and distribution must provide for an accounting of the receipt and disposition of drugs and biologicals. The procedures established to prevent unauthorized usage and distribution must provide for an accounting of	Review of following document(s): Binder - CAH Pharmacy Policies and Procedures Binder - CAH Agreements and Contracts Review of open and closed medical records Facility inspection, including dispensation of drugs, drug labeling and expiration dates, and drug storage Interview with chief pharmacist and pharmacy staff Interviews with all clinical staff regarding familiarity with medication-related policies and procedures

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C276 continued	(iv) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.	The pharmacist, in consultation with appropriate CAH staff and committees, is to develop and implement guidelines, protocols, policies and procedures for the provision of pharmaceutical services that ensure patient safety through the appropriate control and distribution of medications, medication-related devices, and biologicals. All prescribers' medication orders (except in emergency situations) should be reviewed for appropriateness by a pharmacist before the first dose is dispensed. Appropriate monitoring of medication therapy should be conducted. Medication-therapy monitoring includes an assessment of: (a) therapeutic appropriateness of a patient's medication regimen; (b) therapeutic duplication in the patient's medication regimen; (c) Appropriateness of the route and method of administration; (d) medication-medication, medication-food, medication-laboratory test and medication-disease interactions; (e) clinical and laboratory data to evaluate the efficacy of medication therapy to anticipate or evaluate toxicity and adverse effects; and (f) physical signs and clinical symptoms relevant to the patient's medication therapy. Sterile products should be prepared and labeled in a suitable environment by appropriately trained and qualified personnel. The pharmacy should participate in CAH decisions about emergency medications stored in the kits must be consistent with standards of practice and appropriate for a specified age group or disease treatment as well as consistent with applicable Federal and State laws. The pharmacy should be involved in the evaluation, use and monitoring of drug delivery systems, administration devices and automated drug-dispensing machines. The evaluation and monitoring should include the potential for medication errors.	Review of following document(s): Binder – CAH Pharmacy Policies and Procedures Binder – CAH Agreements and Contracts Review of open and closed medical records Facility inspection, including dispensation of drugs, drug labeling and expiration dates, and drug storage Interview with chief pharmacist and pharmacy staff Interviews with all clinical staff regarding familiarity with medication-related policies and procedures

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C276 continued	(iv) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.	Dispensation of Drugs Medications must be prepared safely. Safe preparation procedures could include: (a) Only the pharmacy compounds or admixes all sterile medications, intravenous admixtures, or other drugs except in emergencies or when not feasible (for example, when the product's stability is short); (b) whenever medications are prepared, staff uses safety materials and equipment while preparing hazardous medications; (c) wherever medications are prepared, staff uses techniques to ensure accuracy in medication preparation; (d) whenever medications are prepared, staff uses appropriate techniques to avoid contamination during medication preparation, which include, but are not limited, to the following – using clean or sterile technique as appropriate; maintaining clean, uncluttered, and functionally separate areas for product preparation to minimize the possibility of contamination; using a laminar airflow hood or other appropriate environment while preparing any intravenous (IV) admixture in the pharmacy, any sterile product made from non-sterile ingredients, or any sterile product that will not be used with 24 hours; and visually inspecting the integrity of the medications. Drug Storage All drugs and biologicals must be kept in a locked room or container. If the container is mobile or readily portable, when not in use, it must be stored in a locked room, monitored location, or secured location that will ensure the security of the drugs or biologicals. All drugs and biologicals must be stored in a manner to prevent access by unauthorized individuals. Persons without legal access to drugs or biologicals cannot have unmonitored access to drugs or biologicals cannot have unmonitored access to drugs or biologicals cannot have keys to medication storage rooms, carts, cabinets, or containers. Whenever persons without legal access to the drugs or biologicals stored in an area, the CAH would not be considered as in compliance with the requirement to store all drugs and biologicals in a locked storage area.	Review of following document(s): Binder - CAH Pharmacy Policies and Procedures Binder - CAH Agreements and Contracts Review of open and closed medical records Facility inspection, including dispensation of drugs, drug labeling and expiration dates, and drug storage Interview with chief pharmacist and pharmacy staff Interviews with all clinical staff regarding familiarity with medication-related policies and procedures

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C276 continued	(iv) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.	Nursing Medication Carts, Anesthesia Carts, and Other Medication Carts When not in use, nursing medication carts, anesthesia carts, and other medication carts (hereafter referred to as "carts") containing drugs or biologicals must be locked or stored in a locked storage room. When carts are not in use, locked carts that contain drugs or biologicals must be stored in a locked room, monitored area, or secure location. If a cart containing drugs or biologicals is in use and unlocked, someone with legal access to the drugs and biologicals in the cart must be close by and directly monitoring the cart. That person could be a nurse, a physician, or other individual who in accordance with state and federal law and CAH policy has legal access to the drugs and biologicals in the cart. That person must monitor the cart and be aware of other people's activities near the cart. He/she is responsible for the security of the drugs and biologicals in the cart. System for Labeling and Management of Outdated Drugs The CAH must have a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable drugs and biologicals are not available for patient use. See also NAC 449.343, NAC 449.373	Review of following document(s): Binder – CAH Pharmacy Policies and Procedures Binder – CAH Agreements and Contracts Review of open and closed medical records Facility inspection, including dispensation of drugs, drug labeling and expiration dates, and drug storage Interview with chief pharmacist and pharmacy staff Interviews with all clinical staff regarding familiarity with medication-related policies and procedures
C277	(v) Procedures for reporting adverse drug reactions and errors in the administration of drugs.	Written procedures should require that medication errors and adverse drug reactions be reported immediately to the practitioner who ordered the drug. An entry, including the medication administered and the drug reaction, should be entered into the patient's medical record. Unexpected or significant adverse drug reactions should also be reported to the Food and Drug Administration in accordance with the MedWatch program. There must be a process to report serious adverse drug reactions to the FDA in accordance with the MedWatch program. It is important to flag new types of mistakes as they occur and create systems to prevent their recurrences. The system should work through those mistakes and continually improve and refine things, based on what went wrong.	Review of following document(s): Binder – CAH Pharmacy Policies and Procedures Binder – CAH Agreements and Contracts CAH formulary Review of open and closed medical records Facility inspection, including dispensation of drugs, drug labeling and expiration dates, and drug storage Interview with chief pharmacist and pharmacy staff Interviews with all clinical staff regarding policies on reporting and documentation of medication errors and adverse drug reactions

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C277 continued	(v) Procedures for reporting adverse drug reactions and errors in the administration of drugs.	Reduction of medication errors and adverse reactions can be achieved by effective reporting systems that proactively identify causative factors and are used to implement corrective actions to reduce or prevent reoccurrences. To facilitate reporting, the facility should adopt a medication error and adverse drug reaction (ADR) definition that is broad enough in scope to capture "near misses" and suspected ADRs as well as actual medication errors and ADRs. For high risk medications and high-risk patients (pediatric, geriatric or patients with renal or hepatic impairment) there should be systems in place to minimize adverse drug events. Such systems could include but not limited to: checklists, dose limits, preprinted orders, special packaging, special labeling, double-checks and written guidelines. One example of a definition is the National Coordinating Council Medication Error Reporting and Prevention definition of a medication error. "Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use." In addition to broad scope definitions, the facility must also proactively identify medication errors and adverse drug reactions. Reliance solely on incident reporting fails to identify the majority of adverse drug events. Proactive identification includes observation of medications passes, concurrent and retrospective review of patient's clinical records, ADR surveillance team, implementation of medication usage evaluations for high-alert drugs and identification of indicator drugs or "patient signals" that, when ordered, or noted automatically generate a drug regimen review for a potential adverse drug event.	Review of following document(s): Binder – CAH Pharmacy Policies and Procedures Binder – CAH Agreements and Contracts CAH formulary Review of open and closed medical records Facility inspection, including dispensation of drugs, drug labeling and expiration dates, and drug storage Interview with chief pharmacist and pharmacy staff Interviews with all clinical staff regarding policies on reporting and documentation of medication errors and adverse drug reactions

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C277 continued	(v) Procedures for reporting adverse drug reactions and errors in the administration of drugs.	The facility must have a method by which to measure the effectiveness of its reporting system so as to identify whether or not its system(s) is identifying as many medication errors and adverse drug reactions that would be expected for the size and scope of services provided by their CAH. Such methods could include use of established benchmarks or studies on reporting rates published in peer-reviewed journals. To improve incident reporting the facility should adopt a non-punitive system with the focus on the system and not the involved health care professionals. The facility should have immediately available sufficient texts and other resources on drug therapy. The pharmacist also should be readily available by telephone or other means to discuss drug therapy, interactions, side effects, dosage etc., with practitioners to assist in drug selection and with nursing personnel to assist in the identification of drug-induced problems. The CAH should have policies and procedures to actively identify potential and actual adverse drug events. Proactive identification could include: (a) Direct observation of medication administration; (b) review of patient's clinical records; and (c) identification of patient signals that would warrant immediate review of patient's medication therapy and implementation of medication use evaluation studies. The CAH should have a means to incorporate external alerts and/or recommendations from national associations and governmental agencies for review and facility policy and procedure revision consideration. National associations could include Institute for Safe Medications Practice, National Coordination Council for Medication Error Reporting and Prevention and Joint Commission for Accreditation of Health Care Facilities, Sentinel Event Reports. Governmental agencies may include; Food and Drug Administration, Med Watch Program, and Agency for Health Care Research and Quality.	Review of following document(s): Binder - CAH Pharmacy Policies and Procedures Binder - CAH Agreements and Contracts CAH formulary Review of open and closed medical records Facility inspection, including dispensation of drugs, drug labeling and expiration dates, and drug storage Interview with chief pharmacist and pharmacy staff Interviews with all clinical staff regarding policies on reporting and documentation of medication errors and adverse drug reactions

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C277 continued	(v) Procedures for reporting adverse drug reactions and errors in the administration of drugs.	Provision of pharmaceutical services must meet the needs of the patients' therapeutic goal by promoting a safe medication use process that ensures optimal selection of medications, dose, dosage form, frequency, route, duration of therapy and that substantially reduces or eliminates adverse drug events and duplication of treatment. The CAH pharmacy must ensure that drug orders are accurate and that medications are administered as ordered. When medications are returned unused, the pharmacy should determine the reason the medication was not used. For example, did the patient refuse the medication, was there a clinical reason the medication was not used, was the medication not used due to error? Policies and procedures to minimize drug errors should include: (a) High-alert medications with dosing limits, administration guidelines, packaging, labeling and storage; (b) limiting the variety of medication-related devices and equipment. For example, limit the types of general-purpose infusion pumps to one or two; (c) availability of up-to-date medication information; (d) availability of pharmacy expertise such as having a pharmacist available on-call when pharmacy does not operate 24 hours a day; (e) standardization of prescribing and communication practices; (f) avoidance of certain abbreviations; (g) all elements of the order such as dose, strength, units (metric), route, frequency, and rate; (h) alert systems for look-alike and sound-alike drug names; (i) use of facility approved pre-printed order sheets whenever possible; (j) a voluntary, non-punitive, reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions); (k) the preparation, distribution, administration and proper disposal of hazardous medications; (l) medication recalls; (m) policies and procedures are reviewed and amended secondary to facility-generated reports of adverse drug events.	Review of following document(s): Binder – CAH Pharmacy Policies and Procedures Binder – CAH Agreements and Contracts CAH formulary Review of open and closed medical records Facility inspection, including dispensation of drugs, drug labeling and expiration dates, and drug storage Interview with chief pharmacist and pharmacy staff Interviews with all clinical staff regarding policies on reporting and documentation of medication errors and adverse drug reactions

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C278	(vi) A system for identifying, reporting, investigating and controlling infectious and communicable diseases of patients and personnel.	The CAH must have an active surveillance program that includes specific measures for prevention, early detection, control, education, and investigation of infections and communicable diseases in the CAH. There must be a mechanism to evaluate the effectiveness of the program and to provide corrective action when necessary. The program must include implementation of nationally recognized systems of infection control guidelines to avoid sources and transmission of infections and communicable diseases as recommended by organizations such as the Centers for Disease Control and Prevention (CDC) Guidelines for Prevention and Control of Nosocomial Infections, the CDC Guidelines for Preventing the Transmission of Tuberculosis in Health Care Facilities, the Occupational Health and Safety Administration (OSHA) regulations, and the Association for Professionals in Infection Control and Epidemiology (APIC) infection control guidelines, etc.). The active infection control program should have policies that address the following: (a) Definition of nosocomial infections and communicable diseases; (b) measures for identifying, investigating, and reporting nosocomial infections and communicable diseases; (c) measures for assessing and identifying patients and health care workers, including CAH personnel, contract staff (e.g., agency nurses, housekeeping staff), and volunteers, at risk for infections and communicable diseases; (d) methods for obtaining reports of infections and communicable diseases; (e) measures for inpatients and health care workers, including all CAH personnel, contract such as agency nurses, housekeeping staff, and volunteers, in a timely manner; (e) measures for the prevention of infections, especially infections caused by organisms that are antibiotic resistant or in other ways epidemiologically important; device-related infections (e.g., those associated with intravascular devices, ventilators, tube feeding, indwelling urinary catheters, etc.); surgical site infections; and those infections associated with	Review of following document(s): Binder – CAH Infection Control Policies and Procedures Binder – CAH QA Plan Infection and incidence reports Infection surveillance logs Infection control committee meeting minutes and agenda Facility inspection Interviews with QA Manager and Designated Infection Control Officer

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C278 continued	(vi) A system for identifying, reporting, investigating and controlling infectious and communicable diseases of patients and personnel.	(g) provision of a safe environment consistent with nationally recognized infection control precautions, such as the current CDC recommendations for the identified infection and/or communicable disease; (h) isolation procedures and requirements for infected or immunosuppressed patients; (i) use and techniques for standard precautions; (j) education of patients, family members and caregivers about infections and communicable diseases; (k) methods for monitoring and evaluating practices of asepsis; (l) techniques for hand washing, respiratory protections, asepsis, sterilization, disinfection, food sanitation, housekeeping, fabric care, liquid and solid waste disposal, needle disposal, separation of clean from dirty, as well as other means for limiting the spread of contagion; (m) authority and indications for obtaining microbiological cultures from patients; (n) a requirement that disinfectants, antiseptics, and germicides be used in accordance with the manufacturers' instructions to avoid harming patients, particularly central nervous system effects on children; (o) orientation of all new CAH personnel to infections, communicable diseases, and to the infection control program; (p) measures for the screening and evaluation of health care workers, including all CAH staff, contract workers such as agency nurses, housekeeping staff, and volunteers, for communicable diseases; (q) employee health policies regarding infectious diseases and when infected or ill employees, including contract workers and volunteers, must not render patient care and/or must not report to work; (r) a procedure for meeting the reporting requirements of the local health authority; (s) procedures for working with local, State, and Federal health authorities in emergency preparedness situations; (t) policies and procedures developed in coordination with Federal, State, and local emergency preparedness and health authorities to address communicable disease threats and outbreaks; and (u) provision for program evaluation and revision of the progra	Review of following document(s): Binder - CAH Infection Control Policies and Procedures Binder - CAH QA Plan Infection and incidence reports Infection surveillance logs Infection control committee meeting minutes and agenda Facility inspection Interviews with QA Manager and Designated Infection Control Officer

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C278 continued	(vi) A system for identifying, reporting, investigating and controlling infectious and communicable diseases of patients and personnel.	Designated Infection Control Officer The CAH must designate in writing an individual or group of individuals, qualified through education, training, experience, and certification or licensure, as an infection control officer or officers. An infection control committee may delegate responsibility for infection functions, in accordance with CAH policy. The infection control officer or officers must develop and implement policies governing the control of infections and communicable diseases. The infection control officer(s) is responsible for: (a) implementing policies governing asepsis and infection control; (b) developing a system for identifying, investigating, reporting, and preventing the spread of infections and communicable diseases among patients and CAH personnel, including contract staff and volunteers; (c) identifying, investigating and reporting infections and outbreaks of communicable diseases among patients and CAH personnel, including contract staff and volunteers, especially those occurring in clusters; (d) preventing and controlling the spread of infections and communicable diseases among patients and staff; (e) cooperating with CAH-wide orientation and inservice education programs; (f) cooperating with other departments and services in the performance of quality assurance activities; and (h) cooperating with disease control activities of the local health authority. It is recommended that the infection control officer or officers maintain a log of all incidents related to infections and communicable diseases, including those identified through employee health services. The log is not limited to nosocomial infections. All incidents of infection and communicable diseases should be included in the log. The log documents infections and communicable diseases, contract staff and volunteers).	Review of following document(s): Binder - CAH Infection Control Policies and Procedures Binder - CAH QA Plan Infection and incidence reports Infection surveillance logs Infection control committee meeting minutes and agenda Interviews with QA Manager and Designated Infection Control Officer

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C278 continued	(vi) A system for identifying, reporting, investigating and controlling infectious and communicable diseases of patients and personnel.	The chief executive officer (CEO), the medical staff and the director of nursing (DON) must ensure that the CAH-wide Quality Assurance (QA) program and staff inservice training programs address problems identified through the infection control program. The CEO, the medical staff, and the DON are responsible for implementing corrective action plans to address problems identified by the infection control officer(s). These plans should be evaluated for effectiveness and revised if needed, and documentation concerning corrective actions and outcomes should be maintained. Note: Surveyors will be examining evidence that demonstrates that the CAH's infection control program is incorporated into the facility-wide quality assurance program and that the actual infection control policies and procedures. See also NAC 449.322	Review of following document(s): Binder – CAH Infection Control Policies and Procedures Binder – CAH QA Plan Infection and incidence reports Infection surveillance logs Infection control committee meeting minutes and agenda Interviews with QA Manager and Designated Infection Control Officer
C279	(vii) If the CAH furnishes inpatient services, procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of §485.625(i) is met with respect to inpatients receiving post-hospital SNF care.	A CAH is not required to prepare meals itself and is free to obtain meals under contract with another supplier, but the CAH is responsible for the quality of arranged services on the same basis as if CAH employees had provided those services. The food and dietetic services must be organized, directed and staffed in such a manner to ensure that the nutritional needs of the patients are met in accordance with practitioners' orders and recognized dietary practices. Policies and Procedures for Dietary Services The CAH should have written policies and procedures that address at least the following: (a) Availability of a diet manual and therapeutic diet menus to meet patients' nutritional needs; (b) frequency of meals served; (c) system for diet ordering and patient tray delivery; (d) accommodation of non-routine occurrences such as enteral nutrition (tube feeding), total parenteral nutrition, peripheral parenteral nutrition, change in diet orders, early/late trays, nutritional supplements, etc.;(e) integration of the food and dietetic service into the CAH-wide QA and Infection	Review of following document(s): Binder – CAH Dietary Department Policies and Procedures, esp., current diet plans and approval of these plans by medical staff Therapeutic diet manual CAH personnel files A sample of patient menus Review of open and closed medical records Facility inspection Interviews with Dietary Manager and staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C279 continued	(vii) If the CAH furnishes inpatient services, procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of §485.625(i) is met with respect to inpatients receiving post-hospital SNF care.	Control programs; (f) guidelines for acceptable hygiene practices of food service personnel; and (h) guidelines for kitchen sanitation. Compliance with Recognized Dietary Practices The CAH must be in compliance with Federal and State licensure requirements for food and dietary personnel as well as food service standards, laws and regulations. Director of Food and Dietetic Services The CAH must have an employee (either on staff or contracted) who: (a) Serves as director of the food and dietetic services; (b) is responsible for daily management of the dietary services; and (c) is qualified by experience or training. The service director may be either an employee on staff or under contract, who has been granted the authority and delegated responsibility by the CAH's governing body and medical staff for the operation of the dietary services. This authority and delegated responsibility includes the daily management of the service, implementing training programs for dietary staff, and ensuring that established policies and procedures are maintained that address at least the following: (a) safety practices for food handling; (b) emergency food supplies; (c) orientation, work assignments, supervision of work and personnel performance; (d) menu planning, purchasing of foods and supplies, and retention of essential records such as cost, menus, personnel, training records, QA reports, etc.; and (e) dietary service QA program. Additionally, the service director must demonstrate, through education, experience and/or specialized training, the qualifications necessary to manage the service, appropriate to the scope and complexity of the food service operation. Qualified Dietitian A qualified dietitian must supervise the nutritional aspects of patient care. The dietitian can be part of the CAH staff, work under contract, may be full or part time, and is responsible for all inpatient nutrition including swing bed services. The dietitian's responsibilities include, but are not limited to: (a) approving patient menus and nutri	Review of following document(s): Binder – CAH Dietary Department Policies and Procedures, esp., current diet plans and approval of these plans by medical staff Therapeutic diet manual CAH personnel files A sample of patient menus Review of open and closed medical records Facility inspection Interviews with Dietary Manager and staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C279 continued	(vii) If the CAH furnishes inpatient services, procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of \$485.625(i) is met with respect to inpatients receiving post-hospital SNF care.	(c) performing and documenting nutritional assessments and evaluating patient tolerance to therapeutic diets when appropriate; (d) collaborating with other CAH services (e.g., medical staff, nursing services, pharmacy service, social work service, etc.) to plan and implement patient care as necessary in meeting the nutritional needs of the patients; and (e) maintaining pertinent patient data necessary to recommend, prescribe, or modify therapeutic diets as needed to meet the nutritional needs of the patients. If the qualified dietitian does not work full-time, and when the dietitian is not available, the CAH must make adequate provisions for dietary consultation that meets the needs of the patients. The frequency of consultation depends on the total number of patients, their nutritional needs and the number of patients requiring therapeutic diets or other nutritional supplementation. Dietary Support Staff There must be administrative and technical personnel competent in their respective duties. This competency is demonstrated through education, experience and specialized training appropriate to the task(s) assigned. Personnel files should include documentation that each staff member is competent in their respective duties. Recognized Dietary Practices Nutritional needs must be met in accordance with orders of the practitioner responsible for the care of the patients. Recognized dietary practices include following current national standards for recommended Dietary Allowances (RDA) or the Dietary Reference Intake (DRI) of the Food and Nutrition Board of the National Research Council. Menus provided by the CAH must be nutritional needs of its patients, screening criteria should be developed to identify patients at nutritional risk. If a patient is	Review of following document(s): Binder – CAH Dietary Department Policies and Procedures, esp., current diet plans and approval of these plans by medical staff Therapeutic diet manual CAH personnel files A sample of patient menus Review of open and closed medical records Facility inspection Interviews with Dietary Manager and staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C279 continued	(vii) If the CAH furnishes inpatient services, procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of §485.625(i) is met with respect to inpatients receiving post-hospital SNF care.	identified as an altered nutritional status, a nutritional assessment should be performed on the patient. In addition to the initial nutritional assessment, the patient should be re-evaluated as necessary to ensure their ongoing nutritional needs are met. Examples of patients who may require a nutritional assessment include: (a) All patients requiring artificial nutrition by any means (i.e., enteral nutrition (tube feeding), total parenteral nutrition, or peripheral parenteral nutrition); (b) patients whose medical condition, surgical intervention, or physical status interferes with their ability to ingest, digest or absorb nutrients; (c) patients whose diagnosis or presenting signs/symptoms indicates a compromised nutritional status (e.g., anorexia nervosa, bulimia, electrolyte imbalances, dysphagia, malabsorption, end stage organ diseases, etc.); and (d) patients whose medical condition can be adversely affected by their nutritional intake (e.g., diabetes, congestive heart failure, patients taking certain medications, renal diseases, etc.). Therapeutic diets must be prescribed by the practitioner responsible for the care of the patient. Therapeutic diets should be: (a) Prescribed in writing by a qualified practitioner or a qualified dietitian; (b) documented in the patient's medical record including information about the patient's tolerance to the therapeutic diet as ordered; and (c) evaluated for nutritional adequacy. A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.	Review of following document(s): Binder – CAH Dietary Department Policies and Procedures, esp., current diet plans and approval of these plans by medical staff Therapeutic diet manual CAH personnel files A sample of patient menus Review of open and closed medical records Facility inspection Interviews with Dietary Manager and staff
C280	(4) These policies are reviewed at least annually by the group of professional personnel required under paragraph (a)(2) of this section, and reviewed as necessary by the CAH.	Are patient care policies reviewed on an annual basis by the professional group described in §485.635(a)(2), i.e., by the facility's "CAH Committee" or "CAH Policies and Procedures Committee"? Note: Annual review is a new standard as a CAH.	Review of following document(s): Meeting minutes and agenda – CAH Policies and Procedures Committee Binder – CAH Agreements and Contracts Facility inspection Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C281	(b) Standard: Direct services (1) General. The CAH staff furnishes as direct services, those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These direct services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.	The CAH must provide outpatient and emergency room services as direct services at the CAH campus through the use of CAH personnel. The CAH can choose the level of services to be offered. They may offer only the basic services required by this CoP and State law or they may offer a more complex range of services. However, all the outpatient and emergency services offered must be provided at the CAH campus as direct services. Outpatient Services are a required direct service of the CAH. All outpatient services that the CAH provides to its patients must meet the needs of the patients, in accordance with acceptable standards of practice. The CAH must provide services, equipment, staff, and facilities adequate to provide the outpatient services for the scope of practices appropriate to the scope and complexity of services offered. The outpatient services may be offered at specific times. The CAH is not required to offer outpatient services 24/7 except for emergency room services. The CAH's outpatient services must be integrated with inpatient services (e.g., medical records, radiology, laboratory, surgical services, anesthesia services, other diagnostic services, etc), as appropriate to the outpatient services offered. The CAH must have written policies in place to ensure the integration of outpatient services, including an established method of communication between outpatient service departments to corresponding inpatient services. The outpatient services department must be accountable to a single individual who directs the overall operation of the department. The CAH should define in writing the qualifications and competencies necessary to direct the outpatient services. Qualifications include necessary education, experience and specialized training, consistent with State law, and acceptable standards of practice. Adequate types and numbers of qualified professional and nonprofessional personnel must be available to provide patients with the appropriate level of care and services offered by the CAH'S outpatient d	Review of following document(s): Binder – CAH Patient Services Policies and Procedures Review of open and closed medical records Facility inspection and observation of staff delivering health care services to patients Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C281 continued	(b) Standard: Direct services (1) General. The CAH staff furnishes as direct services, those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These direct services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.	Rehabilitation Services Rehabilitation services are optional CAH services and can include physical therapy, occupational therapy, audiology, and/or speech pathology services. If a CAH provides any degree of rehabilitative services to its patients, either directly or under arrangement, either inpatient or outpatient, the services must be organized and staffed to ensure the health and safety of patients. This includes providing rehabilitative services in accordance with practitioner orders and acceptable standards of practice. Acceptable standards of practice include any standards that are set forth in Federal or State laws, regulations or guidelines, as well as standards and recommendations promoted by nationally recognized professional organizations such as the American Physical Therapy Association, American Occupational Therapy Association, American Occupational Therapy Association, American College of Physicians, and the American Medical Association etc. If rehabilitative services are provided, the CAH must provide, or ensure, the appropriate equipment and types and numbers of qualified personnel necessary to furnish the rehabilitation services offered by the CAH in accordance with acceptable standards of practice. The scope of rehabilitation services offered by the CAH, both directly or under contract, should be defined in written policies and procedures and approved by the Medical staff. Each service, whether provided directly or through a contract, must function with established lines of authority and responsibility to ensure the health and safety of patients. There must be an adequate number of qualified staff available when needed to evaluate each patient, initiate the plan of treatment, and supervise supportive personnel when they furnish rehabilitation services. The number of qualified staff is based on the type of patients treated and the frequency, duration, and complexity of the treatment required.	Review of following document(s): Binder – CAH Patient Services Policies and Procedures Review of open and closed medical records Facility inspection and observation of staff delivering health care services to patients Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C281 continued	(1) General. The CAH staff furnishes as direct services, those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These direct services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.	The rehabilitation service must be accountable to an individual that directs the overall operation of the service. The director of the services must demonstrate through education, experience, and/or specialized training that he/she has the necessary knowledge, experience and capabilities to properly supervise and administer the service. The director may be part-time, full-time, and/or under contract. If part-time, the time spent directing the service should be appropriate with the scope of services provided. The medical staff must define in writing the required qualifications and competencies for rehabilitation staff in each program or service offered. Qualifications should include the necessary education, experience, specialized training, and if applicable, licensure requirements appropriate for assigned responsibilities consistent with State law. At least one qualified professional, of the applicable discipline, must be on site when needed to: (a) Perform an initial evaluation of each patient for whom rehabilitative services were ordered; (b) initiate the plan of treatment based on the initial evaluation, input from family/caregivers and in accordance with the orders of the practitioner responsible for the care of the patient; and (c) supervise supportive personnel when they furnish services. Each patient must have an individualized plan of treatment, based on the patient's specific rehabilitation needs, input from family/caregivers and therapeutic treatment goals, that are established in writing prior to the initiation of treatment. At a minimum, the treatment plan must: (a) Be established by the practitioner ordering the service in collaboration with an individual qualified to provide the services; (b) be based on the patient's individualized assessment; (c) include the type, amount, frequency and duration of services; (d) include measurable short-term and long-term goals; and (f) Be reviewed and revised as necessary to reflect changes in the patient's response to therapeutic intervention.	Review of following document(s): Binder – CAH Patient Services Policies and Procedures Review of open and closed medical records Facility inspection and observation of staff delivering health care services to patients Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C281 continued	(b) Standard: Direct services (1) General. The CAH staff furnishes as direct services, those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These direct services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.	Updated treatment goals should reflect the changes in the patient's status. Changes to the treatment plan must be documented in writing and supported by clinical record information such as evaluation, test results, interdisciplinary staff conferences or MD/DO orders. The activities described in the written plan of treatment must be within the scope of practice, State licensure, or certifications of the individual performing the activity.	Review of following document(s): Binder – CAH Patient Services Policies and Procedures Review of open and closed medical records Facility inspection and observation of staff delivering health care services to patients Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C282	(2) <u>Laboratory services</u> . The CAH provides, as direct services, basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under Section 353 of the Public Health Service Act (42 U.S.C. 236(a)) (See the laboratory requirements specified in Part 493 of this Chapter) – (i) Chemical examination of urine by stick or tablet method or both (including urine ketones); (ii) Hemoglobin or hematocrit; (iii) Blood glucose; (iv) Examination of stool specimens for occult blood; (v) Pregnancy tests; and (vi) Primary culturing for transmittal to a certified laboratory.	Basic laboratory services must be provided directly at the CAH campus by CAH staff in order to facilitate the immediate diagnosis and treatment of the patient. The CAH must have a current Clinical Laboratory Improvement Act (CLIA) certificate or waiver for all tests performed. The provision of laboratory services that exceed the requirements for basic laboratory services is an optional requirement. The CAH must maintain or have available laboratory services, either directly or through arrangement, whenever its patients need those services. The CAH may maintain laboratory services at the CAH or may make laboratory services available through contractual agreements except for the required basic services. The scope and complexity of the CAH laboratory service must be adequate to meet the needs of its patients. All laboratory services, whether direct or contractual must be provided in accordance with CLIA requirements. Every CAH laboratory must be operating under a current CLIA certificate appropriate to the level of services performed, including a waiver certificate. The CAH must provide basic emergency laboratory services 24 hours a day, 7 days a week. The medical staff should determine which laboratory services are to be immediately available to meet the emergency laboratory needs of patients who may be currently at the CAH or those patients who may arrive at the CAH in an emergency condition and how the services are to be provided. The emergency laboratory services available should reflect the scope and complexity of the CAH'S operation and be provided in accordance with Federal and State law, regulations and guidelines and acceptable standards of practice. The laboratory must have written instructions for the collection, preservation, transportation, receipt, and reporting of tissue specimen results.	Review of following document(s): Binder – CAH Agreements and Contracts Binder – CAH Laboratory Department Policies and Procedures Logs and other records contained in the laboratory Appropriate and current CLIA certificate Facility inspection Interviews with staff, esp., laboratory department manager and staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C283	(3) <u>Radiology services.</u> Radiology services furnished at the CAH are provided as direct services by staff qualified under State law, and do not expose CAH patients or staff to radiation hazards.	Radiological services must be provided by the CAH as direct services at the CAH campus by CAH staff. The CAH must maintain and have available diagnostic radiological services to meet the needs of their patients. These services must be available at all times. The CAH can choose the level of services offered. They may offer only a minimal set of services or a more complex range of services (including nuclear medicine) according to the needs of the patients of the CAH. While the CAH must directly provide all radiology services in the CAH, the interpretation of roentgenograms may be contracted out.	Review of following document(s): Binder – CAH Agreements and Contracts Binder – CAH Radiology Department Policies and Procedures Equipment inspection records Facility inspection Interviews with staff, esp., radiology department manager and staff
		All radiological services provided by the CAH, including diagnostic, therapeutic, and nuclear medicine, must be provided in accordance with acceptable standards of practice and must meet professionally approved standards for safety. The scope and complexity of radiological services offered should be specified in writing and approved by the medical staff and governing body (or responsible individual) of the CAH.	
		Acceptable standards of practice include maintaining compliance with appropriate Federal and State laws, regulations and guidelines governing radiological services, including facility licensure and/or certification requirements, as well as any standards and recommendations promoted by nationally recognized professions such as the American Medical Association, American College of Radiology, etc.	
		The CAH must adopt policies and procedures that provide safety for patients and personnel. The CAH must implement and ensure compliance with its established safety standards. The policies should contain safety standards for at least: (a) Adequate radiation shielding for patients, personnel and facilities; (b) labeling of radioactive materials, waste, and hazardous areas; (c) transportation of radioactive materials between locations within the CAH; (d) security of radioactive materials, including determining who may have access to radioactive materials; (e) testing of equipment for radiation hazards; (f) maintenance of personal radiation monitoring devices; (g) ensuring that files, scans, and	

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C283 continued	(3) Radiology services. Radiology services furnished at the CAH are provided as direct services by staff qualified under State law, and do not expose CAH patients or staff to radiation hazards.	other image records are kept in a secure area and are readily retrievable; and (h) training radiology staff on how to operate the equipment safely, perform tests offered by the facility and on the management of emergency radiation hazards and accidents. There should be written policies, developed and approved by the medical staff, consistent with State law, to designate which personnel are qualified to use the radiological equipment and administer procedures. The CAH must maintain records for all radiology procedures performed. At a minimum, the records should include copies of reports and printouts, and any films, scans or other image records, as appropriate. The CAH should have written policies and procedures that ensure the integrity of authentication and protect the privacy of radiology records. See also NAC 449.376 and NAC 449.377	Review of following document(s): Binder – CAH Agreements and Contracts Binder – CAH Radiology Department Policies and Procedures Equipment inspection records Facility inspection Interviews with staff, esp., radiology department manager and staff
C284	(4) Emergency procedures. In accordance with the requirements of §485.618, the CAH provides as direct services, medical emergency procedures as a first response to common life-threatening injuries and acute illnesses.	Is one person responsible for ensuring the availability of emergency equipment and supplies? How are your emergency procedures documented? See also NAC 449.331, NAC 449.349	Review of following document(s): □ Binder – CAH Agreements and Contracts □ Binder – CAH Emergency Department Policies and Procedures Facility inspection Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C285	(c) Standard: Services provided through agreements or arrangements. (1) The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including –	Individual agreements or arrangements should be well defined, but need not be contractual. They should describe routine procedures (e.g., for obtaining outside laboratory tests); and there should be evidence in the agreement or arrangement that the governing body (or responsible individual) is responsible for these services provided under agreement or arrangement. Individual agreements or arrangements should be revised when the nature and scope of services provided has changed. The governing body (or responsible individual) has the responsibility for ensuring that CAH services are provided according to acceptable standards of practice, irrespective of whether the services are provided directly by CAH employees or indirectly by arrangement. The governing body must take actions through the CAH's QA program to: assess the services furnished directly by CAH staff and those services provided under arrangement, identify quality and performance problems, implement appropriate corrective or improvement activities, and to ensure the monitoring and sustainability of those corrective or improvement activities. See also NAC 449.331	Review of following document(s): □ Binder – CAH Agreements and Contracts Facility inspection Interviews with staff
C286	(i) Inpatient hospital care;	Is there an arrangement or agreement with one or more hospitals to provide inpatient care to patients the hospital cannot handle (i.e., greater than 96 hours or acuity level beyond capabilities of CAH)? See sample Transfer Agreement	Review of following document(s): □ Binder – CAH Agreements and Contracts, including transfer agreements Facility inspection Interviews with staff
C287	(ii) Services of doctors of medicine or osteopathy; and	Are there arrangements or agreements with one or more doctors of medicine or osteopathy to meet its requirements at §485.631(b)?	Review of following document(s): □ Binder – CAH Agreements and Contracts Facility inspection Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C288	(iii) Additional or specialized diagnostic and clinical laboratory services that are not available at the CAH.	Laboratories that provide additional diagnostic and clinical laboratory services to a CAH by agreement or arrangement must be in compliance with CLIA requirements in 42 CFR Part 493 of this chapter. These laboratories will be surveyed separately for compliance with Part 493. Are there arrangements or agreements for specialized diagnostic and clinical laboratory services that are necessary to provide care for its patients (e.g., MRI)?	Review of following document(s): □ Binder – CAH Agreements and Contracts □ Binder – CAH Laboratory Department Policies and Procedures Facility inspection Interviews with staff
C289	(iv) Food and other services to meet inpatients' nutritional needs to the extent these services are not provided directly by the CAH.	If the CAH has an outside contract for nutritional services, how does the CAH ensure that it has arrangements or agreements for the provision of nutritional services that meet this requirement?	Review of following document(s): □ Binder – CAH Agreements and Contracts □ Binder – CAH Dietary Department Policies and Procedures Facility inspection Interviews with staff
C290	(2) If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated.	 Transferred patients were accepted and provided with inpatient care, as needed, at hospitals to which they were transferred? Patients referred for diagnostic and/or laboratory tests had these tests performed as requested by the practitioner responsible for the patient? Physicians and/or suppliers of services are providing services in the manner described in the arrangement or agreement? This will require that your transfer agreement with other hospital allows you to at least periodically check these items after you transfer a patient. 	Review of following document(s): □ Binder – CAH Agreements and Contracts □ Review of open and closed medical records Interviews with staff
C291	(3) The CAH maintains a list of all services furnished under arrangements or agreements. The list describes the nature and scope of the services provided.	Is there a list of all services which are provided under contract? How current is this list?	Review of following document(s): □ Binder – CAH Agreements and Contracts Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C292	(4) The person principally responsible for the operation of the CAH under §485.627(b)(2) of this chapter is also responsible for the following – (i) Services furnished in the CAH whether or not they are furnished under arrangements or agreements; and	Is the CAH administrator/CEO responsible for all services provided through arrangements or agreements?	Review of following document(s): □ Binder – CAH Governing Body By Laws □ Binder – CAH Job Descriptions □ CAH Organizational Chart Interviews with staff
C293	(ii) Ensuring that a contractor of services (including one for shared services and joint ventures) furnishes services that enable the CAH to comply with all applicable conditions of participation and standards for the contracted services.	Do all contracted services meet all of the appropriate Conditions of Participation and standards for contracted services? Note: Hospital contractors must meet all Medicare conditions of participation (e.g., non-discrimination compliance) and standards for contracted services.	Review of following document(s): □ Binder – CAH Governing Body By Laws □ Binder – CAH Job Descriptions Interviews with staff and temporary staff
C294	(d) Standard: Nursing services. Nursing services must meet the needs of patients.	In order to meet the needs of patients, nursing services must be a well-organized service of the CAH and under the direction of a registered nurse. The CAH and the director of the nursing service are responsible for the clinical activities of all nursing to include the clinical activities of all non-CAH nursing personnel (contract, agency, or volunteer). The CAH and the director of nursing service ensure that all CAH nursing staff and each non-CAH nursing staff person is adequately trained and oriented, is adequately supervised, that their clinical activities are evaluated, and that all nursing personnel know the CAH policies and procedures. An appropriately qualified CAH-employed RN should conduct the supervision and evaluation of the clinical activities of each non-CAH nursing staff. See also NAC 449.361 – 449.3628	Surveyors will observe the nursing care in progress to determine the adequacy of staffing and to assess the delivery of care. Other sources of information to use in the evaluation of the nursing services are: nursing care plans, medical records, accident and investigative reports, staffing schedules, nursing policies and procedures, credentialing and training files (including contracted staff), and QA activities and reports. Surveyors will also review the method for orienting non-CAH staff to CAH policies and procedures. The orientation should include at least the following: (a) The CAH and the unit; (b) emergency procedures; (c) Nursing services policies and procedures; and (d) safety policies and procedures.

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C295	(1) A registered nurse must provide (or assign to other personnel) the nursing care of each patient, including patients at a SNF level of care in a swing-bed CAH. The care must be provided in accordance with the patient's needs and the specialized qualifications and competence of the staff available.	The nursing service ensures that patient needs are met by ongoing assessments of patients' needs and provides nursing staff to meet those needs. There must be sufficient personnel to respond to the appropriate medical needs and care of the patient population being serviced. An RN must make all patient care assignments. The director of the nursing service and the CAH are to ensure that nursing personnel with the appropriate education, experience, licensure, competence and specialized qualifications are assigned to provide nursing care for each patient in accordance with the individual needs of each patient.	Review of following document(s): Binder – CAH Nursing Department Policies and Procedures Nursing staff/work schedules Review of open and closed medical records Observation of nursing care provided to patients Interviews with DoN, nursing staff and temporary nursing staff to assess familiarity with CAH nursing requirements
C296	(2) A registered nurse or, where permitted by State law, a physician assistant, must supervise and evaluate the nursing care for each SNF level of care in a swing-bed CAH.	An RN (or PA where State law permits) must supervise and evaluate the nursing care for each patient. Evaluation would include assessing the patient's care needs as well as the patient's response to interventions. Does a registered nurse supervise the nursing care for each patient? Are staffing schedules current? Do staffing schedules correlate to the number and acuity of patients, including swing-bed patients? Will staffing schedules demonstrate that acuity and numbers of patients are considered in staffing?	Review of following document(s): Binder – CAH Nursing Department Policies and Procedures Nursing staff/work schedules Review of open and closed medical records Observation of nursing care provided to patients Interviews with DoN, nursing staff and temporary nursing staff to assess familiarity with CAH nursing requirements
C297	(3) All drugs, biologicals, and intravenous medications must be administered by or under the supervision of a registered nurse, a doctor of medicine or osteopathy or, where permitted by State law, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws.	All drugs and biologicals and intravenous medications must be administered by or under the supervision of a RN, MD, DO or PA as permitted by Nevada law, in accordance with written or signed orders, accepted standards of practice, and Federal and State laws. As permitted by Nevada law and CAH policy, LPN's may administer medications if they are under the supervision of an RN, MD, DO or PA if permitted by State law. Drugs and biologicals must be prepared and administered in accordance with Federal and State laws. Drugs and biologicals must be prepared and administered in accordance with the orders of the practitioner or practitioners responsible for the patient's care. Drugs and biologicals must be prepared and administered in accordance with accepted standards of practice.	Review of following document(s): Binder – CAH Nursing Department Policies and Procedures Nursing staff/work schedules Review of 6-12 nursing care plans Review of open and closed medical records Observation of nursing care provided to patients Interviews with DoN, nursing staff and temporary nursing staff to assess familiarity with CAH nursing requirements

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C297 continued	(3) All drugs, biologicals, and intravenous medications must be administered by or under the supervision of a registered nurse, a doctor of medicine or osteopathy or, where permitted by State law, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws.	All orders for drugs and biologicals, including verbal orders, must be legible, timed, dated and authenticated with a signature by the practitioner or practitioners responsible for the care of the patient. All entries in the medical record must be legible, timed, dated and authenticated. A telephone or verbal order is written in the medical record by a nurse or other professional in accordance with State law and CAH policy as being able to accept verbal orders. The written verbal order must be legible and includes the date, time, the order, the name of the ordering practitioner and the signature of the accepting individual. The ordering practitioner must date and time the order at the time he or she signs the order and must sign a verbal order as soon as possible which would be the earlier of the following: (a) The next time the prescribing practitioner provides care to the patient, assesses the patient, or documents information in the patient's medical record, or (b) the prescribing practitioner signs or initials the verbal order within time frames consistent with Federal and State law or regulation and CAH policy. The content of verbal orders should be clearly communicated. The entire verbal order should be repeated back to the prescriber. All verbal orders must be documented in the patient's medical record, and be reviewed and countersigned by the prescriber as soon as possible. In some instances, the ordering practitioner may not be able to authenticate his or her verbal order (e.g., the ordering practitioner gives a verbal order which is written and transcribed, and then is "off duty" for the weekend or an extended period of time). In such cases, it is acceptable for a covering practitioner. The signature indicates that the covering practitioner assumes responsibility for his/her colleague's order as being complete, accurate and final.	Review of following document(s): Binder - CAH Nursing Department Policies and Procedures Nursing staff/work schedules Review of 6-12 nursing care plans Review of open and closed medical records Observation of nursing care provided to patients Interviews with DoN, nursing staff and temporary nursing staff to assess familiarity with CAH nursing requirements

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C297 continued	(3) All drugs, biologicals, and intravenous medications must be administered by or under the supervision of a registered nurse, a doctor of medicine or osteopathy or, where permitted by State law, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws.	This practice must be addressed in the CAH's policy. However, a qualified practitioner such as a physician assistant or nurse practitioner may not "co-sign" a MD/DO's verbal order or otherwise authenticate a medical record entry for the MD/DO who gave the verbal order. When used, verbal orders must be used infrequently. Therefore, it is not acceptable to allow covering practitioners to authenticate verbal orders for convenience or to make this common practice. When assessing compliance with this requirement, surveyors review the frequency and practice of using verbal orders within the CAH. Verbal orders are orders for medications, treatments, intervention or other patient care that are communicated as oral, spoken communications between senders and receivers face to face or by telephone. Verbal communication of orders should be limited to urgent situations where immediate written or electronic communication is not feasible. CAHs should establish policies and procedures that: (a) Describe limitations or prohibitions on use of verbal orders; (b) provide a mechanism to ensure validity/authenticity of the prescriber; (c) list the elements required for inclusion in a complete verbal order; (d) describe situations in which verbal orders may be used; (e) list and define the individuals who may send and receive verbal orders; and (f) provide guidelines for clear and effective communication of verbal orders. CAHs should promote a culture in which it is acceptable, and strongly encouraged, for staff to question prescribers when there are any questions or disagreements about verbal orders. Questions about verbal orders should be resolved prior to the preparation, or dispensing, or administration of the medication. Elements that should be included in any verbal medication order include: (a) Name of patient; (b) age and weight of patient, when appropriate; (c) date and time of the order; (d) drug name; (e) dosage form (e.g., tablets, capsules, inhalants);	Review of following document(s): Binder - CAH Nursing Department Policies and Procedures Nursing staff/work schedules Review of 6-12 nursing care plans Review of open and closed medical records Observation of nursing care provided to patients Interviews with DoN, nursing staff and temporary nursing staff to assess familiarity with CAH nursing requirements

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C297 continued	(3) All drugs, biologicals, and intravenous medications must be administered by or under the supervision of a registered nurse, a doctor of medicine or osteopathy or, where permitted by State law, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws.	(f) exact strength or concentration; (g) dose, frequency, and route; (h) quantity and/or duration; (i) purpose or indication; (j) specific instructions for use; and (k) name of prescriber.	Review of following document(s): Binder – CAH Nursing Department Policies and Procedures Nursing staff/work schedules Review of 6-12 nursing care plans Review of open and closed medical records Observation of nursing care provided to patients Interviews with DoN, nursing staff and temporary nursing staff to assess familiarity with CAH nursing requirements
C298	(4) A nursing care plan must be developed and kept current for each patient.	Nursing care planning starts upon admission. It includes planning the patient's care while in the CAH as well as planning for discharge to meet post-CAH needs. A nursing care plan is based on assessing the patient's nursing care needs and developing appropriate nursing interventions in response to those needs. The nursing care plan is kept current by ongoing assessments of the patient's needs and the patient's response to interventions, and updating or revising the patient's nursing care plan in response to assessments. The nursing care plan is part of the patient's medical record and must comply with the requirements for patient records. Is there a complete and current nursing care plan for each patient? Is discharge planning consideration part of every patient evaluation? See also NAC 449.332	Review of following document(s): Binder – CAH Nursing Department Policies and Procedures Nursing care plans Review of open and closed medical records Observation of nursing care provided to patients Interviews with DoN, nursing staff and temporary nursing staff to assess familiarity with CAH nursing requirements
C300	§485.638 Condition of participation: Clinical records.	See also NAC 449.379	
C301	(a) <u>Standard: Records system.</u>(1) The CAH maintains a clinical records system in accordance with written policies and procedures.	The CAH must have a system of patient records, pertinent medical information, author identification, and record maintenance that ensures the integrity of the authentication and protects the security of all record entries. The medical record system must correctly identify the author of every medical record entry. The	Review of following document(s): □ Binder – CAH Medical Records Policies and Procedures □ Review of open and closed medical records Interviews with Medical Records Director and staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C301 continued	(a) Standard: Records system. (1) The CAH maintains a clinical records system in accordance with written policies and procedures.	medical record system must protect the security of all medical record entries. The medical record system must ensure that medical record entries are not lost, stolen, destroyed, altered, or reproduced in an unauthorized manner. All locations where medical records are stored or maintained must ensure the integrity, security and protection of the records. The CAH must have a system in place that ensures that the identity of the author of each entry is correct. The author of every entry must take a specified action to identify himself/herself as the author (or responsible person) of the entry, the time and dating of the entry, that the entry is accurate, and that he/she takes responsibility for accuracy of the entry. If the CAH uses computer entries there must be a security system in place to ensure the integrity of the record system, to ensure that the author of each entry is correctly identified, to ensure that record entries are not altered or lost, that limits access to medical records to only authorized persons, and ensures that records are not released to unauthorized individuals. For the purposes of this regulation, electronic signatures comply with those medical record entries that include a requirement for a signature. There should be a current list of authenticated signatures, as well as a list of computer codes and signature stamps (when used for authorship purposes) that have been authorized by the governing body and are protected by adequate safeguards. The CAH policies and procedures should provide for appropriate sanctions for unauthorized or improper use of computer codes or signature stamps. The CAH must maintain a medical record for each inpatient and outpatient evaluated or treated in any part or location of the CAH. A unit record for both inpatients and outpatients may be used; however, when two different systems are used they must be appropriately cross referenced. When a patient reimbursement status changes from acute care services to swing bed services, a single medical record may be use	Review of following document(s): Binder – CAH Medical Records Policies and Procedures Review of open and closed medical records Interviews with Medical Records Director and staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C301 continued	(a) Standard: Records system. (1) The CAH maintains a clinical records system in accordance with written policies and procedures.	as the record is sectioned separately. Both sections must include admission and discharge orders, progress notes, nursing notes, graphics, laboratory support documents, any other pertinent documents, and discharge summaries. The medical record must be properly filed and retained. The CAH must have a medical recording system that ensures the prompt retrieval of any medical record, of any patient evaluated or treated at any location of the CAH within the past 6 years. The medical record must be accessible. The CAH must have a medical record system that allows the medical record of any patient, inpatient or outpatient, evaluated and/or treated at any location of the CAH within the past 6 years to be accessible by appropriate staff, 24 hours a day, 7 days a week, whenever that medical record may be needed.	Review of following document(s): □ Binder – CAH Medical Records Policies and Procedures □ Review of open and closed medical records Interviews with Medical Records Director and staff
C302	(2) The records are legible, complete, accurately documented, readily accessible, and systematically organized.	All medical records must be accurately written. The CAH must ensure that all medical records accurately and completely document all orders, test results, evaluations, treatments, interventions, care provided and the patient's response to those treatments, interventions and care. For CAH surveys that are conducted after the initial certification survey, a sample (at least 10% of the census and not more than 30) of CAH active and closed clinical records will be assessed to determine if records are prepared and maintained in accordance with the requirements of §485.638(2) and (4).	Review of following document(s): □ Binder – CAH Medical Records Policies and Procedures □ Review of open and closed medical records Interviews with Medical Records Director and staff
C303	(3) A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.	The CAH must have one unified medical record service with a department head that has been appointed by the governing body (or responsible individual). The director of medical records must have responsibility for all medical records to include both inpatient and outpatient records.	Review of following document(s): □ Binder – CAH Medical Records Policies and Procedures □ Review of open and closed medical records □ CAH Organizational Chart Interviews with Medical Records Director and staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C304	(4) For each patient receiving health care services, the CAH maintains a record that includes, as applicable – (i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;	The medical record must include evidence of properly executed informed consent forms for any procedures or surgical procedures specified by the medical staff, or by Federal or State law, if applicable, that require written patient consent. "Informed consent" means the patient or patient representative is given the information, explanations, consequences, and options needed in order to consent to a procedure or treatment. A properly executed consent form contains at least the following: (a) Name of patient, and when appropriate, patient's legal guardian; (b) name of CAH; (c) name of procedure(s); (d) name of practitioner(s) performing the procedures(s); (e) signature of patient or legal guardian; (f) date and time consent is obtained; (g) statement that procedure was explained to patient or guardian; (h) signature of professional person witnessing the consent; and (i) name/signature of person who explained the procedure to the patient or guardian. The medical record must contain information such as progress and nursing notes, documentation, records, reports, recordings, test results, assessments etc. in order to: (a) Justify admission; (b) support the diagnosis; (c) describe the patient's progress; (d) describe the patient's response to medications; and (e) describe the patient's response to interventions, care, treatments, etc The medical record must contain complete information/documentation regarding medical history, assessment of the health status and health care needs of the patient, and a summary of the episode, disposition, and instructions to the patient. This information and documentation is contained in a discharge summary. A "discharge summary" discusses the outcome of the CAH stay, the disposition of the patient, and provisions for follow-up care. Follow-up care provisions include any post-CAH appointments, how post-CAH patient care needs are to be met, and any plans for post-CAH care by providers such as swing-bed services, home health, hospice, nursing homes, or assisted living. A discharge summ	Review of following document(s): Binder – CAH Medical Records Policies and Procedures Review of open and closed medical records, esp. execution of consent forms and discharge instructions Interviews with Medical Records Director and staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C304 continued	(4) For each patient receiving health care services, the CAH maintains a record that includes, as applicable – (i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;	The MD/DO or other qualified practitioner with admitting privileges in accordance with State law and CAH policy, who admitted the patient is responsible for the patient during the patient's stay in the CAH. This responsibility would include developing and entering the discharge summary. The MD/DO may delegate writing the discharge summary to other qualified health care personnel such as nurse practitioners and physician assistants to the extent recognized under State law or a State's regulatory mechanism. The MD/DO may also delegate writing the discharge summary to another MD/DO who is familiar with the patient.	Review of following document(s): □ Binder – CAH Medical Records Policies and Procedures □ Review of open and closed medical records, esp. execution of consent forms and discharge instructions Interviews with Medical Records Director and staff
C305	(ii) Reports of physical examinations, diagnostic and laboratory test results, including laboratory services, and consultative findings;	All or part of the history and physical exam (H & P) may be delegated to other practitioners in accordance with State law and CAH policy, but the MD/DO must sign the H & P and assume full responsibility for the H & P. This means that a nurse practitioner or a physician assistant meeting these criteria may perform the H & P. Are reports of physical examinations, diagnostic and laboratory test results, and consultative findings signed by the appropriate practitioner?	Review of following document(s): □ Binder – CAH Medical Records Policies and Procedures □ CAH Medical Staff By-Laws □ Review of open and closed medical records Interviews with Medical Records Director and staff
C306	(iii) All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature graphics, progress notes describing the patient's response to treatments; and	The requirement means that the stated information is necessary to monitor the patient's condition and that this and other necessary information must be in the patient's medical record. In order for necessary information to be used it must be promptly filed in the medical record so that health care staff involved in the patient's care can access/retrieve this information in order to monitor the patient's condition and provide appropriate care. The medical record must contain: (a) all practitioner's orders (properly authenticated); (b) all nursing notes; (c) all reports of treatment (including complications and CAH-acquired infections); (d) all medication records (including unfavorable reactions to drugs); (e) all radiology reports; (f) all laboratory reports; (g) all vital signs; and (h) all other information necessary to monitor the patient's condition.	Review of following document(s): □ Binder – CAH Medical Records Policies and Procedures □ Review of open and closed medical records Interviews with Medical Records Director and staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C306 continued	(iii) All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature graphics, progress notes describing the patient's response to treatments; and	All medical records must be promptly completed. Every medical record must be complete with all documentation of orders, diagnosis, evaluations, treatments, test results, consents, interventions, discharge summary, and care provided along with the patient's response to those treatments, interventions, and care.	Review of following document(s): □ Binder – CAH Medical Records Policies and Procedures □ Review of open and closed medical records Interviews with Medical Records Director and staff
C307	(iv) Dated signatures of the doctor of medicine or osteopathy or other health care professional.	Entries in the medical record may be made only by individuals as specified in CAH and medical staff policies. All entries in the medical record must be timed, dated, and authenticated, and a method established to identify the author. The identification may include written signatures, initials, computer key, or other code. When rubber stamps are authorized, the individual whose signature the stamp represents shall place in the administrative offices of the CAH a signed statement to the effect that he/she is the only one who has the stamp and uses it. There shall be no delegation to another individual. A list of computer or other codes and written signatures must be readily available and maintained under adequate safeguards. There shall be sanctions for improper or unauthorized use of stamp, computer key, or other code signatures. The CAH must have policies and procedures in place and operational before an electronic medical record system would be deemed acceptable. The parts of the medical record that are the responsibility of the MD/DO must be authenticated by this individual. When non-MD/DOs have been approved for such duties as taking medical histories or documenting aspects of physical examination, such information shall be appropriately authenticated by the responsible MD/DO. Any entries in the medical record by house staff or non-MD/DOs that require counter signing by supervisory or attending medical staff members shall be defined in the medical staff rules and regulations.	Review of following document(s): Binder – CAH Medical Records Policies and Procedures CAH list of authenticated signatures written initials, codes and stamps Review of open and closed medical records Interviews with Medical Records Director and staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C307 continued	(iv) Dated signatures of the doctor of medicine or osteopathy or other health care professional.	All entries in the medical record must be authenticated. Authentication would include at a minimum: (a) The CAH has a method to establish the identify of the author of each entry. This would include verification of the author of faxed orders/entries or computer entries; (b) the author takes a specific action to verify that the entry is his/her entry or that he/she is responsible for the entry, that the entry is accurate; and (c) the timing of the entry is noted and correct. Timing documents the time and date of each entry (orders, reports, notes etc.). Timing establishes when an order was given, when an activity happened or when an activity is to take place. Timing and dating entries are necessary for patient safety and quality of care. Timing and dating of entries establishes a baseline for future actions or assessments and establishes a timeline of events. Many patient interventions or assessments are based on time intervals or time lines of various signs, symptoms, or events. There must be a specific action by the author to indicate that the entry is, in fact, verified and accurate. Failure to disapprove an entry within a specific time period is not acceptable as authentication. A system of auto-authentication in which a MD/DO or other practitioner authenticates a report before transcription is not consistent with these requirements. There must be a method of determining that the practitioner did, in fact, authenticate the document after it was transcribed.	Review of following document(s): Binder - CAH Medical Records Policies and Procedures CAH list of authenticated signatures written initials, codes and stamps Review of open and closed medical records Interviews with Medical Records Director and staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C308	(b) Standard: Protection of record information. (1) The CAH maintains the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use.	The CAH has sufficient safeguards to ensure that access to all information regarding patients is limited to those individuals designated by law, regulation, policy; or duly authorized as having a need to know. No unauthorized access or dissemination of clinical records is permitted. Clinical records are kept secure and are only viewed when necessary by those persons having a part in the patient's care. The right to confidentiality means safeguarding the content of information, including patient paper records, video, audio, and/or computer stored information from unauthorized disclosure without the specific informed consent of the individual, parent of a minor child, or legal guardian. CAH staff and consultants, hired to provide services to the individual, should have access to only that portion of information that is necessary to provide effective responsive services to that individual. Confidentiality applies to both central records and clinical record information that may be kept at dispersed locations. See sample policy C308 See also NAC 449.379	Review of following document(s): Binder – CAH Medical Records Policies and Procedures Review of open and closed medical records Interviews with Medical Records Director and staff
C309	(2) Written policies and procedures govern the use and removal of records from the CAH and the condition for the release of information.	The CAH's patient record system must ensure the security of patient records. The CAH must ensure that unauthorized individuals cannot gain access to patient records and that individuals cannot alter patient records. Patient records must be secure at all times and in all locations. This includes open patient records for patients who are currently inpatients in the CAH and outpatients in outpatient clinics. Are patient records left unsecured or unattended? Are patient records unsecured or unattended in hallways, patient rooms, nurses stations, or on counters where an unauthorized person could gain access to patient records? If the CAH uses electronic patient records, are appropriate security safeguards in place? Is access to patient records controlled? See sample policy C309	Review of following document(s): Binder – CAH Medical Records Policies and Procedures Review of open and closed medical records Interviews with Medical Records Director and staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C310	(3) The patient's consent is required for release of information not required by law.	No records are released without the patients consent or under appropriate legal authority.	Review of following document(s): Binder – CAH Medical Records Policies and Procedures Review of open and closed medical records Interviews with Medical Records Director and staff
C311	(c) Standard: Retention of records. The records are retained for at least 6 years from date of last entry, and longer if required by State statute, or if the records may be needed in any pending preceding.	The records are retained for at least 6 years from date of last entry, and longer if required by State statute, or if the records may be needed in any pending proceeding. Are medical records retained in their original or legally reproduced form, for a period of at least 6 years? Facsimiles received on thermal sensitive paper is reproduced on to regular paper. Is there a policy which states all medical records will be retained at least six years? See sample policy C311	Review of following document(s): □ Binder – CAH Medical Records Policies and Procedures □ Review of open and closed medical records Facility inspection Interviews with Medical Records Director and staff
C320	§485.639 Condition of Participation: Surgical services. Surgical procedure must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the CAH in accordance with the designation requirements under paragraph (a) of this section.	The provision of surgical services is an optional CAH service. However, if a CAH provides any degree of surgical services to its patients, the services must be organized and staffed in such a manner to ensure the health and safety of patients. Surgical services that are performed in a safe manner would be performed in accordance with acceptable standards of practice. In accordance with acceptable standards of practice includes maintaining compliance with applicable Federal and State laws, regulations and guidelines governing surgical services or surgical service locations, as well as, any standards and recommendations promoted by or established by nationally recognized professional organizations (e.g., the American Medical Association, American College of Surgeons, Association of Operating Room Nurses, Association for Professionals in Infection Control and Epidemiology, etc.) Additionally, the quality of the CAH's outpatient surgical services must be consistent with the CAH's inpatient surgical services.	Review of following document(s): Binder – CAH Governing Body By Laws Binder – CAH Medical Staff By Laws Binder – CAH Surgery Department Policies and Procedures CAH Organizational Chart CAH Operating Room Register Review of open and closed medical records with a surgical encounter Inspection of operating rooms and surgical suites Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C320 continued	§485.639 Condition of Participation: Surgical services. Surgical procedure must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the CAH in accordance with the designation requirements under paragraph (a) of this section.	Supervision in the OR The operating room (inpatient and outpatient) must be supervised by an experienced staff member authorized by Nevada law. The supervisor's experience could include education, background working in surgical services, and specialized training in the provision of surgical services/management of surgical service operations. The CAH should address its required qualifications for the supervisor of the CAH'S operating rooms in its policies. If the CAH utilizes LPN or operating room technicians as "scrub nurses", those personnel must be under the supervision of an RN who is immediately available to physically intervene and provide care, as required in Nevada law. See also NAC 449.385 and 449.388 When the CAH offers surgical services, the CAH must provide the appropriate equipment and types and numbers of qualified personnel necessary to furnish the surgical services offered by the CAH in accordance with acceptable standards of practice. The scope of surgical services provided by the CAH should be defined in writing and approved by the medical staff. Surveyors will check to see that hospital surgical services are characterized by: (a) Equipment and supplies sufficient so that the type of surgery conducted can be preformed in a manner that will not endanger the health and safety of the patient; (b) operative and recovery areas limited in access; (c) appropriate aseptic techniques in place; (d) appropriate cleaning between surgical cases; (e) suitable equipment available for rapid and routine sterilization of operating room materials; (f) sterilized materials properly labeled, and stored in a manner to ensure sterility; (g) operating room attire suitable for the kind of surgical cases performed. For example, persons working in the operating suite must wear clean surgical costumes in lieu of their ordinary clothing; and (h) surgical costumes are to be designed for maximum skin and hair coverage.	Review of following document(s): Binder - CAH Governing Body By Laws Binder - CAH Medical Staff By Laws Binder - CAH Surgery Department Policies and Procedures CAH Organizational Chart CAH Operating Room Register Review of open and closed medical records with a surgical encounter Inspection of operating rooms and surgical suites Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C320 continued	§485.639 Condition of Participation: Surgical services. Surgical procedure must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the CAH in accordance with the designation requirements under paragraph (a) of this section.	Policies and procedures must be written, implemented and enforced. Surgical services' policies must be in accordance with acceptable standards of medical practice and surgical patient care. Policies governing surgical care should contain information on: (a) Resuscitative techniques; (b) aseptic technique and scrub procedures; (c) care of surgical specimens; (d) appropriate protocols for all surgical procedures, specific or general in nature, and include a list of equipment, materials, and supplies to properly carry out job assignments; (e) the cleaning of operating rooms after each use; (f) sterilization and disinfection procedures; (g) acceptable operating room attire; (h) care of anesthesia equipment; and (I) special provision for infected or contaminated patients. Pre-operative History and Physical (H & P) A complete history and physical must be conducted in accordance with acceptable standards of practice, and the written document placed on the medical record, prior to surgery. All or part of the H & P may be delegated to other practitioners in accordance with State law and CAH policy, but the surgeon must sign the H & P and assume full responsibility for the H & P. This means that a nurse practitioner or a physician assistant, meeting these criteria, may perform the H & P. In all circumstances, when an H & P has been conducted, but is not present on the chart prior to surgery, or in emergency situations where a complete H & P cannot be conducted prior to surgery, a brief admission note on the chart is necessary. The note should include at a minimum critical information about the patient's condition including pulmonary status, cardiovascular status, BP, vital signs, etc. Informed Consent A properly executed informed consent form contains at least the following: (a) name of patient, and when appropriate, patient's legal guardian; (b) name of CAH; (c) name of procedure(s) or important aspects of the procedure(s), as well as the name(s) and specific significant surgical tasks that will be conducted by practi	Review of following document(s): Binder - CAH Governing Body By Laws Binder - CAH Medical Staff By Laws Binder - CAH Surgery Department Policies and Procedures CAH Organizational Chart CAH Operating Room Register Review of open and closed medical records with a surgical encounter Inspection of operating rooms and surgical suites Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C320 continued	§485.639 Condition of Participation: Surgical services. Surgical procedure must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the CAH in accordance with the designation requirements under paragraph (a) of this section.	and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues.); (e) signature of patient or legal guardian; (f) date and time consent is obtained; (g) statement that procedure was explained to patient or guardian; (h) signature of professional person witnessing the consent; and (i) name/signature of person who explained the procedure to the patient or guardian. The responsible practitioner must disclose to the patient any information necessary to enable the patient to evaluate a proposed medical or surgical procedure before submitting to it. Informed consent requires that a patient have a full understanding of that to which he or she has consented. An authorization from a patient who does not understand what he/she is consenting to is not informed consent. Patients must be given sufficient information to allow them to make intelligent choices from among the alternative courses of available treatment for their specific ailments. Informed consent must be given despite a patient's anxiety or indecisiveness. The responsible practitioner must provide as much information about treatment options as is necessary based on a patient's personal understanding of the practitioner's explanation of the risks of treatment and the probable consequences of the treatment. Informed consent means the patient or patient representative is given (in a language or means of communication he/she understands) the information needed in order to consent to a procedure or treatment. An informed consent would include at least: an explanation of the nature and purpose of the proposed procedures, risks and consequences of the procedures, risks and prognosis if no treatment is rendered, the probability that the proposed procedure will be successful, and alternative methods of treatment (if any) and their associated risks and benefits. Furthermore, informed consent would include that the patient is informed as to who will actually perform surgical interventions that are planned. When practitioners ot	Review of following document(s): Binder - CAH Governing Body By Laws Binder - CAH Medical Staff By Laws Binder - CAH Surgery Department Policies and Procedures CAH Organizational Chart CAH Operating Room Register Review of open and closed medical records with a surgical encounter Inspection of operating rooms and surgical suites Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C320 continued	§485.639 Condition of Participation: Surgical services. Surgical procedure must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the CAH in accordance with the designation requirements under paragraph (a) of this section.	than the primary surgeon will perform important parts of the surgical procedures, even when under the primary surgeon's supervision, the patient must be informed of who these other practitioners are, as well as, what important tasks each will carry out. Post-Operative Care/Recovery Adequate provisions for immediate post-operative care means: (a) Post operative care must be in accordance with acceptable standards of practice. (b) The post-operative care area or recovery room is a separate area of the CAH. Access is limited to authorized personnel. (c) Policies and procedures specify transfer requirements to and from the recovery room. Depending on the type of anesthesia and length of surgery, the post-operative check before transferring the patient from the recovery room should include some of the following: Level of activity; respirations; blood pressure; level of consciousness; and patient color. If the patients are not transferred to the recovery room, determine that provisions are made for close observation until they have regained consciousness, e.g., direct observation by an RN in the patient's room. Operating Room Register The register should include at least the following information: (a) Patient's name; (b) patient's CAH identification number; (c) date of the operation; (d) inclusive or total time of the operation; (e) name of the surgeon and any assistant(s); (f) name of nursing personnel (scrub and circulating); (g) type of anesthesia used and name of person administering it; (h) operation performed; (i) pre- and post-op diagnosis; and (j) age of patient. The operative report would include at least: (a) Name and CAH identification number of the patient; (b) date and times of the surgery; (c) name(s) of the surgeon(s) and assistants or other practitioners who performed surgical tasks (even when performing those tasks under supervision); (d) pre-operative and post-operative diagnosis; (e) name of the specific surgical procedure(s) performed; (f) type of anesthesia administered; (g) complications, if	Review of following document(s): Binder - CAH Governing Body By Laws Binder - CAH Medical Staff By Laws Binder - CAH Surgery Department Policies and Procedures CAH Organizational Chart CAH Operating Room Register Review of open and closed medical records with a surgical encounter Inspection of operating rooms and surgical suites Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C320 continued	§485.639 Condition of Participation: Surgical services. Surgical procedure must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the CAH in accordance with the designation requirements under paragraph (a) of this section.	significant surgical tasks that were conducted by practitioners other than the primary surgeon/practitioner (significant surgical procedures include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues); and (j) prosthetic devices, grafts, tissues, transplants, or devices implanted, if any.	Review of following document(s): Binder – CAH Governing Body By Laws Binder – CAH Medical Staff By Laws Binder – CAH Surgery Department Policies and Procedures CAH Organizational Chart CAH Operating Room Register Review of open and closed medical records with a surgical encounter Inspection of operating rooms and surgical suites Interviews with staff
C321	(a) Standard: Designation of qualified practitioners. The CAH designates the practitioners who are allowed to perform surgery for CAH patients, in accordance with its approved policies and procedures, and with State scope of practice laws. Surgery is performed only by — (1) A doctor of medicine or osteopathy, including an osteopathy practitioner recognized under section 1101(a)(7) of the Act; (2) A doctor of dental surgery or dental medicine; or (3) A doctor of podiatric medicine.	Surgical privileges should be reviewed and updated at least every 2 years. A current roster listing each practitioner's specific surgical privileges must be available in the surgical suite and area/location where the scheduling of surgical procedures is done. A current list of surgeons suspended from surgical privileges or whose surgical privileges have been restricted must be retained in these area/locations. The CAH must delineate the surgical privileges of all practitioners performing surgery and surgical procedures. The medical staff is accountable to the governing body (or responsible individual) for the quality of care provided to patients. The medical staff bylaws must include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. Surgical privileges are granted in accordance with the competencies of each practitioner. The medical staff appraisal procedures must evaluate each individual practitioner's training, education, experience, and demonstrated competence as established by the CAH's QA program, credentialing process, the practitioner's adherence to CAH policies and procedures, and in accordance with scope of practice and other State laws and regulations.	Review of following document(s): Binder – CAH Surgery Department Policies and Procedures, including methods and policy for reviewing surgical privileges Binder – CAH Medical Staff By Laws Credential files for physicians and mid-level providers Review of open and closed medical records Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C321 continued	(a) Standard: Designation of qualified practitioners. The CAH designates the practitioners who are allowed to perform surgery for CAH patients, in accordance with its approved policies and procedures, and with State scope of practice laws. Surgery is performed only by – (1) A doctor of medicine or osteopathy, including an osteopathy practitioner recognized under section 1101(a)(7) of the Act; (2) A doctor of dental surgery or dental medicine; or (3) A doctor of podiatric medicine.	The CAH must specify the surgical privileges for each practitioner that performs surgical tasks. This would include practitioners such as MD/DOs, dentists, oral surgeons, podiatrists, RN first assistants, nurse practitioners, surgical physician assistants, surgical technicians, etc. When a practitioner may perform certain surgical procedures under supervision, the specific tasks/procedures and the degree of supervision (to include whether or not the supervising practitioner is in the same OR in line of sight) be delineated in that practitioner's surgical privileges and included on the surgical roster. When practitioners whose scope of practice for conducting surgical procedures requires the supervision of an MD/DO surgeon, the term "supervision" would mean the supervising MD/DO surgeon is present in the same room, working with the same patient. Surgery and all surgical procedures must be conducted by a practitioner who meets the medical staff criteria and procedures for the privileges granted, who has been granted surgical privileges in accordance with those criteria established by the governing body (or responsible individual), and who is working within the scope of those granted and documented privileges.	Review of following document(s): Binder – CAH Surgery Department Policies and Procedures, including methods and policy for reviewing surgical privileges Binder – CAH Medical Staff By Laws Credential files for physicians and mid-level providers Review of open and closed medical records Interviews with staff
C322	(b) Standard: Anesthetic risk and evaluation. A qualified practitioner, as described in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner as described in paragraph (a) of this section.	The pre-anesthesia evaluation must be performed prior to inpatient or outpatient surgery. The pre-anesthesia evaluation must be performed by an individual qualified to administer anesthesia. The pre-operative anesthetic evaluation should include: (a) Notation of anesthesia risk; (b) anesthesia, drug and allergy history; (c) any potential anesthesia problems identified; and (d) patient's condition prior to induction of anesthesia. The post-anesthesia follow-up report must be written on all inpatients and outpatients prior to discharge from surgery and anesthesia services. The post-anesthesia evaluation must be written by the individual who is qualified to administer the anesthesia.	Review of following document(s): Binder – CAH Surgery Department Policies and Procedures Credential files for physicians and mid-level providers Review of open and closed medical records Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C322 continued	(b) Standard: Anesthetic risk and evaluation. A qualified practitioner, as described in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner as described in paragraph (a) of this section.	An MD/DO may delegate the post-anesthesia assessment and the writing of the post-anesthesia follow-up report to practitioners qualified to administer anesthesia in accordance with Nevada law and CAH policy. When delegation of the post-anesthesia follow-up report is permitted, the medical staff must address its delegation requirements and methods in its bylaws. The post-anesthesia follow-up report must be documented in the patient's medical record, whether the patient is an inpatient or outpatient of the CAH, and must include at a minimum: (a) Cardiopulmonary status; (b) level of consciousness; (c) Any follow-up care and/or observations; and (d) any complications occurring during post-anesthesia recovery. See also NAC 449.388	Review of following document(s): □ Binder – CAH Surgery Department Policies and Procedures □ Credential files for physicians and mid-level providers □ Review of open and closed medical records Interviews with staff
C323	(c) Standard: Administration of anesthesia. The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope of practice laws. (1) Anesthetics must be administered only by — (i) A qualified anesthesiologist; (ii) A doctor of medicine or osteopathy other than an anesthesiologist, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act; (iii) A doctor of dental surgery or dental medicine; (iv) A doctor of podiatric medicine; (iv) A certified registered nurse anesthetist, as defined in §410.69(b) of this chapter; or (vi) An anesthesiologist's assistant, as defined in §410.69(b) of this chapter; or (vii) A supervised trainee in an approved educational program, as described in §413.85 or 413.86 of this chapter.	The medical staff bylaws must include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. The CAH must specify the anesthesia privileges for each practitioner that administers anesthesia, or who supervises the administration of anesthesia by another practitioner. The privileges granted must be in accordance with State law and CAH policy. The type and complexity of procedures for which the practitioner may administer anesthesia, or supervise another practitioner supervising anesthesia, must be specified in the privileges granted to the individual practitioner. A dentist, oral surgeon, or podiatrist may administer anesthesia in accordance with State law, their scope of practice and CAH policy. The anesthesia privileges of each practitioner must be specified. Anesthesia privileges are granted in accordance with the practitioner's scope of practice, Nevada law, the individual competencies of the practitioner and the practitioner's compliance with the CAH's credentialing criteria.	Review of following document(s): Binder – CAH Surgery Department Policies and Procedures CAH Medical Staff By-Laws Credential files for physicians and mid-level providers Review of open and closed medical records Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C323 continued	(c) Standard: Administration of anesthesia. The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope of practice laws. (1) Anesthetics must be administered only by — (i) A qualified anesthesiologist; (ii) A doctor of medicine or osteopathy other than an anesthesiologist, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act; (iii) A doctor of dental surgery or dental medicine; (iv) A doctor of podiatric medicine; (v) A certified registered nurse anesthetist, as defined in §410.69(b) of this chapter; or (vi) An anesthesiologist's assistant, as defined in §410.69(b) of this chapter; or (vii) A supervised trainee in an approved educational program, as described in §413.85 or 413.86 of this chapter.	The medical staff bylaws must include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. The CAH must specify the anesthesia privileges for each practitioner that administers anesthesia, or who supervises the administration of anesthesia by another practitioner. The privileges granted must be in accordance with Nevada law and CAH policy. The type and complexity of procedures for which the practitioner may administer anesthesia, or supervise another practitioner supervising anesthesia, must be specified in the privileges granted to the individual practitioner. Anesthesia privileges are granted in accordance with the practitioner's scope of practice, Nevada law, the individual competencies of the practitioner and the practitioner's compliance with the CAH's credentialing criteria. When a CAH permits operating practitioners to supervise CRNA administering anesthesia, the medical staff must specify in the statement of privileges for each category of operating practitioner, the type and complexity of procedures they may supervise. A CRNA may administer anesthesia when under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed (unless supervision is exempted in accordance with §485.639(e)). An anesthesiologist's assistant may administer anesthesia when under the supervision of an anesthesiologist who is immediately available if needed. Available to immediately intervene includes at a minimum, that the supervising anesthesiologist or operating practitioner, as applicable, is: (a) Physically located within the operative suite or in the labor and delivery unit; (b) is prepared to immediately conduct hands-on intervention if needed; and (c) is not engaged in activities that could prevent the supervising practitioner from being able to immediately intervene and conduct hands-on interventions if needed	Review of following document(s): Binder – CAH Surgery Department Policies and Procedures CAH Medical Staff By-Laws Credential files for physicians and mid-level providers Review of open and closed medical records Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C324	(2) In those cases in which a certified registered nurse anesthetist administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner. An anesthesiologist's assistant must be under the supervision of an anesthesiologist.	In all procedures where a CRNA administers anesthesia, the operating practitioner understands and agrees to supervise the anesthetist when applicable. Determine whether CAH regulations in conflict with state licensing regulations?	Review of following document(s): □ Binder – CAH Surgery Department Policies and Procedures □ Credential files for physicians and mid-level providers □ Review of open and closed medical records Interviews with staff
C325	(d) Standard: Discharge. All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure.	Are all patients discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure? Is this reflected in the medical record? Are there policies regarding discharge instructions for post-anesthetic patients? Surveyors will check to see if exceptions to this condition are made by the attending practitioner and documented in the clinical record.	Review of following document(s): □ Binder – CAH Surgery Department Policies and Procedures □ Binder – Discharge Planning Policies and Procedures □ Review of open and closed medical records Interviews with staff
C326	(e) Standard: State exemption. (1) A CAH may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (c)(2) of this section, if the State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter form the Governor must attest that he or she has consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law. (2) The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time, and are effective upon submission.	Note: Any exceptions to this standard must be submitted in writing to the Nevada FLEX Program, the Bureau of Licensure and Certification, and documented with the Nevada Office of Rural Health. The Nevada Rural Health Plan does not currently provide any exception to this standard.	

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C330	§485.641 Condition of participation: Periodic evaluation and quality assurance review.	While conducting the survey, a surveyor may identify a patient care practice or other CAH practice with which the surveyor is unfamiliar. Health care and CAH practice are continually changing due to new laws, regulations and standards of practice. If your facility produces a law, regulation, or standard of practice from a nationally recognized organization, surveyors will evaluate whether the CAH's policies and procedures reflect the law, regulation, or standard of practice. They will also evaluate whether the your facility's actual practice reflects their policies and procedures, as well as the law, regulation or standard of practice. Note: The following conditions regarding "yearly evaluation" would not be applicable at initial survey but the hospital must have a process to show that yearly evaluation will be done annually, as a CAH. See sample policy C330 See also NAC 449.314, 449.3152, and 449.317	Review of following document(s): Binder – CAH Periodic Evaluation and Quality Assurance Plan Meeting minutes and agenda – CAH Policies and Procedures Committee Interviews with staff
C331	 (a) Standard: Periodic evaluation. (1) The CAH carries out or arranges for a periodic evaluation of its total program. The evaluation is done at least once a year and includes review of – 	Note: As a CAH there must be an annual evaluation of services. See sample policy C330	Review of following document(s): Binder – CAH Periodic Evaluation and Quality Assurance Plan Meeting minutes and agenda – CAH Policies and Procedures Committee Interviews with staff
C332	(i) The utilization of CAH services, including at least the number of patients served and the volume of services;	Does yearly evaluation of services include a consideration of volume, number, and utilization of services?	Review of following document(s): Binder – CAH Periodic Evaluation and Quality Assurance Plan Periodic Evaluation and QA Reports Meeting minutes and agenda – CAH Policies and Procedures Committee Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C333	(ii) A representative sample of both active and closed clinical records; and	Yearly evaluation includes review of 10 percent of records. Who is responsible for the review of both active and closed records? How are records selected and reviewed? How does the evaluation process ensure that the sample of records is representative of services furnished? What criteria are utilized in the review of both active and closed records?	Review of following document(s): Binder – CAH Periodic Evaluation and Quality Assurance Plan Periodic Evaluation and QA Reports Meeting minutes and agenda – CAH Policies and Procedures Committee Review of open and closed medical records Interviews with staff
C334	(iii) The CAH's health care policies.	Yearly evaluation and review includes medical-clinical policies of the hospital. What evidence demonstrates that the health care policies of the CAH are evaluated, reviewed, and/or revised as a part of the annual program evaluation? See sample policy C330	Review of following document(s): Binder – CAH Periodic Evaluation and Quality Assurance Plan Periodic Evaluation and QA Reports Meeting minutes and agenda – CAH Policies and Procedures Committee Review of open and closed medical records Interviews with staff
C335	(2) The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and any changes are needed.	Can it be demonstrated that yearly evaluation results in follow-up and action where necessary? How does the CAH use the results of the yearly program evaluation? Were policies, procedures, and/or facility practices changed or revised as a result of the yearly program evaluation?	Review of following document(s): Binder – CAH Periodic Evaluation and Quality Assurance Plan Periodic Evaluation and QA Reports Meeting minutes and agenda – CAH Policies and Procedures Committee Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C336	(b) Standard: Quality assurance. The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. The program requires that —	There is nothing in this requirement to preclude a CAH from obtaining QA through arrangement. Whether the CAH has a freestanding QA program or QA by arrangement, all of the requirements for QA must be met. If a CAH chooses to have a freestanding QA program, the QA program should be facility wide, including all departments and all services provided under contact. For services provided to the CAH under contract, there should be established channels of communication between the contractor and CAH staff. The quality assurance program must be facility-wide, including all departments and all services provided under contract that includes: (a) Ongoing monitoring and data collection; (b) problem prevention, identification and data analysis; (c) identification of corrective actions; (d) implementation of corrective actions; (e) evaluation of corrective actions; and (f) measures to improve quality on a continuous basis. Surveyors will be reviewing your facility's QA plan and all other documents you can provide regarding QA activities (e.g., meeting notes from QA committee meetings, QA reports) to determine the scope and structure of QA activities in your hospital.	Review of following document(s): Binder – CAH Periodic Evaluation and Quality Assurance Plan Periodic Evaluation and QA Reports Meeting minutes and agenda – CAH Policies and Procedures Committee Interviews with staff, especially QA Director
C337	(1) All patient care services and other services affecting patient health and safety, are evaluated;	Is there is a designated quality assurance coordinator? Are patient care services and patient health and safety part of the quality assurance program? How is this information communicated to the medical staff and hospital board?	Review of following document(s): Binder – CAH Periodic Evaluation and Quality Assurance Plan Periodic Evaluation and QA Reports Meeting minutes and agenda – CAH Policies and Procedures Committee Interviews with staff, especially QA Director

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C338	(2) Nosocomial infections and medication therapy are evaluated;	Are there an infection control officer, infection control committee and documented infection control processes?	Review of following document(s): Binder – CAH Periodic Evaluation and Quality Assurance Plan Periodic Evaluation and QA Reports Infection Control Log Meeting minutes and agenda – CAH Policies and Procedures Committee Interviews with staff, especially QA Director
C339	(3) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the CAH are evaluated by a member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH;	Does a doctor of medicine or osteopathy evaluate the quality of care provided by mid-level practitioners? Is clinical performance of mid-level practitioners part of the quality assurance program? Is there provision for action if quality of care concerns are raised with regards to mid-levels? What follow-up actions are prescribed in your facility's QA plan?	Review of following document(s): Binder – CAH Periodic Evaluation and Quality Assurance Plan Periodic Evaluation and QA Reports Meeting minutes and agenda – CAH Policies and Procedures Committee Interviews with staff, especially QA Director
C340	(4) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the CAH are evaluated by – (i) One hospital that is a member of the network when applicable; (ii) One QIO or equivalent entity; or (iii) One other appropriate and qualified entity identified in the	Note: As of September 1, 2004, all CAHs and prospective CAHs must enter into an agreement with Nevada Rural Hospital Partners for quality assurance and credentialing. Any exception to this provision must be submitted to the Nevada Office of Rural Health in writing (see also Tag C 195). Does the hospital have a Memorandum of Understanding with the QIO? Is there is an agreement with another hospital for peer review? See Sample Agreement to Exchange Peer Review Services	Review of following document(s): □ Binder – CAH Agreements and Contracts, i.e., signed agreement between CAH and NRHP Interviews with staff, especially QA Director
C341	(5)(i) The CAH staff considers the findings of the evaluations, including any findings or recommendations of the QIO, and takes corrective action if necessary.	Is there a person designated as a QIO liaison who can go forward with HealthInsight's (Nevada QIO) findings and recommendations?	Review of following document(s): Binder – CAH Periodic Evaluation and Quality Assurance Plan Periodic Evaluation and QA Reports Meeting minutes and agenda – CAH Policies and Procedures Committee Interviews with staff, especially QA Director

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C342	(ii) The CAH also takes appropriate remedial action to address deficiencies found through the quality assurance program.	Can the quality assurance program demonstrate follow- up action, remedial and corrective?	Review of following document(s): Binder – CAH Periodic Evaluation and Quality Assurance Plan Periodic Evaluation and QA Reports Meeting minutes and agenda – CAH Policies and Procedures Committee Interviews with staff, especially QA Director
C343	(iii) The CAH documents the outcome of all remedial action.	Is remedial action, once taken, is further monitored until positive outcomes are demonstrated?	Review of following document(s): Binder – CAH Periodic Evaluation and Quality Assurance Plan Periodic Evaluation and QA Reports Meeting minutes and agenda – CAH Policies and Procedures Committee Interviews with staff
C344	§485.643 Condition of participation: Organ, tissue, and eye procurement.	In general, CAHs must have (a) organ, tissue, and eye procurement policies and procedures; (b) organ, tissue, and eye procurement agreements on file; and (c) evidence of staff education on organ, tissue, and eye procurement.	
C345	The CAH must have and implement written protocols that: (a) Standard: Incorporate an agreement with an OPO designated under 486 of this chapter, under which it must notify, in a timely manner, the OPO or third party designated by the OPO of individuals whose death is imminent or who have died in the CAH. The OPO determines medical suitability for tissue and eye donation and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose;	The CAH must have a written agreement with an Organ Procurement Organization (OPO), designated under 42 CFR Part 486. At a minimum, the written agreement must address the following: (a) The criteria for referral, including the referral of all individuals whose death is imminent or who have died in the CAH; (b) includes a definition of "imminent death"; (c) includes a definition of "timely notification"; (d) addresses the OPO's responsibility to determine medical suitability for organ donation; (e) specifies how the tissue and/or eye bank will be notified about potential donors using notification protocols developed by the OPO in consultation with the CAH-designated tissue and eye bank(s); (f) provides for notification of each individual death in a timely manner to the OPO (or designated third party) in accordance with the terms of the agreement; (g) ensures that the designated requestor training program offered by the OPO has been developed in cooperation with the tissue	Review of following document(s): Binder – CAH Organ, Tissue and Eye Procurement Policies and Procedures Binder – CAH Agreements and Contracts, esp. the CAH-OPO agreement CAH QA Plan Review of closed medical records of patients who have died in the CAH in the past six months Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C345 continued	The CAH must have and implement written protocols that: (a) Standard: Incorporate an agreement with an OPO designated under 486 of this chapter, under which it must notify, in a timely manner, the OPO or third party designated by the OPO of individuals whose death is imminent or who have died in the CAH. The OPO determines medical suitability for tissue and eye donation and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose;	OPO has been developed in cooperation with the tissue bank and eye bank designated by the CAH; (h) permits the OPO, tissue bank, and eye bank access to the CAH's death record information according to a designated schedule, e.g., monthly or quarterly; (i) includes that the CAH is not required to perform credentialing reviews for, or grant privileges to, members of organ recovery teams as long as the OPO sends only "qualified, trained individuals" to perform organ recovery; and (j) the interventions the CAH will utilize to maintain potential organ donor patients so that the patient organs remain viable. The CAH must notify the OPO of every death or imminent death in the CAH. When death is imminent, the CAH must notify the OPO both before a potential donor is removed from a ventilator and while the potential donor's organs are still viable. The CAH should have a written policy, developed in coordination with the OPO and approved by the CAH's medical staff and governing body, to define "imminent death". The definition for "imminent death" should strike a balance between the needs of the OPO and the needs of the CAH's care givers to continue treatment of a patient until brain death is declared or the patient's family has made the decision to withdraw supportive measures. Collaboration between OPOs and CAHs will create a partnership that furthers donation, while respecting the perspective of CAH staff. The definition for "imminent death" might include a patient with severe, acute brain injury who: (a) Requires mechanical ventilation; (b) is in an intensive care unit (ICU) or emergency department; and (c) has clinical findings consistent with a Glascow Coma Score that is less than or equal to a mutually-agreed-upon threshold; — or — MD/DOs are evaluating a diagnosis of brain death; — or — an MD/DO has ordered that life sustaining therapies be withdrawn, pursuant to the family's decision.	Review of following document(s): Binder – CAH Organ, Tissue and Eye Procurement Policies and Procedures Binder – CAH Agreements and Contracts, esp. the CAH-OPO agreement CAH QA Plan Review of closed medical records of patients who have died in the CAH in the past six months Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C345 continued	The CAH must have and implement written protocols that: (a) Standard: Incorporate an agreement with an OPO designated under 486 of this chapter, under which it must notify, in a timely manner, the OPO or third party designated by the OPO of individuals whose death is imminent or who have died in the CAH. The OPO determines medical suitability for tissue and eye donation and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose;	The CAH and their OPO should develop a definition of "imminent death" that includes specific triggers for notifying the OPO about an imminent death. In determining the appropriate threshold for the Glasgow Coma Score (GCS), it is important to remember that if the threshold is too low, there may be too many "premature" deaths or situations where there is a loss of organ viability. Standards for appropriate GCS thresholds may be obtained from the CAH's OPO or organizations such as the Association of Organ Procurement Organizations. Note that a patient with "severe, acute brain injury" is not always a trauma patient. For example, post myocardial infarction resuscitation may result in a patient with a beating heart and no brain activity. The definition agreed to by the CAH and the OPO may include all of the elements listed above or just some of the elements. The definition should be tailored to fit the particular circumstances in each CAH. The CAH may not use "batch reporting" for deaths by providing the OPO with periodic lists of patient deaths, even if instructed to do so by the OPO. If the patient dies during a transfer from one CAH to another, it is the receiving CAH's responsibility to notify the OPO. "Timely notification" means a CAH must contact the OPO by telephone as soon as possible after an individual has died, has been placed on a ventilator due to a severe brain injury, or who has been declared brain dead (ideally within 1 hour). That is, a CAH must notify the OPO while a brain dead or severely brain-injured, ventilator-dependent individual is still attached to the ventilator and as soon as possible after the death of any other individual, including a potential non-heart-beating donor. Even if the CAH does not consider an individual who is not on a ventilator to be a potential donor, the CAH must call the OPO as soon as possible after the death of that individual has occurred.	Review of following document(s): Binder - CAH Organ, Tissue and Eye Procurement Policies and Procedures Binder - CAH Agreements and Contracts, esp. the CAH-OPO agreement CAH QA Plan Review of closed medical records of patients who have died in the CAH in the past six months Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C345 continued	The CAH must have and implement written protocols that: (a) Standard: Incorporate an agreement with an OPO designated under 486 of this chapter, under which it must notify, in a timely manner, the OPO or third party designated by the OPO of individuals whose death is imminent or who have died in the CAH. The OPO determines medical suitability for tissue and eye donation and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose;	Referral by a CAH to an OPO is timely if it is made: (a) As soon as it is anticipated a patient will meet the criteria for imminent death agreed to by the OPO and CAH or as soon as possible after a patient meets the criteria for imminent death agreed to by the OPO and the CAH (ideally, within one hour); and (b) pPrior to the withdrawal of any life sustaining therapies (i.e., medical or pharmacological support). Whenever possible, referral should be made early enough to allow the OPO to assess the patient's suitability for organ donation before brain death is declared and before the option of organ donation is presented to the family of the potential donor. Timely assessment of the patient's suitability for organ donation increases the likelihood that the patient's organs will be viable for transplantation (assuming there is no disease process identified by the OPO that would cause the organs to be unsuitable), ensures that the family is approached only if the patient is medically suitable for organ donation, and ensures that an OPO representative is available to collaborate with the CAH staff in discussing donation with the family. It is the OPO's responsibility to determine medical suitability for organ donation, and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose.	Review of following document(s): Binder - CAH Organ, Tissue and Eye Procurement Policies and Procedures Binder - CAH Agreements and Contracts, esp. the CAH-OPO agreement CAH QA Plan Review of closed medical records of patients who have died in the CAH in the past six months Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C346	(b) Standard: Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage an distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;	The CAH must have an agreement with at least one tissue bank and at least one eye bank. The OPO may serve as a "gatekeeper" receiving notification about every CAH death and should notify the tissue bank chosen by the CAH about potential tissue and eye donors. It is not necessary for a CAH to have a separate agreement with a tissue bank if it has an agreement with its OPO to provide tissue procurement services; nor is it necessary for a CAH to have a separate agreement with an eye bank if its OPO provides eye procurement services. The CAH is not required to use the OPO for tissue or eye procurement but is free to have an agreement with the tissue bank or eye bank of its choice. The tissue banks and eye banks define "usable tissues" and "usable eyes". The requirements of this regulation may be satisfied through a single agreement with an OPO that provides services for organ, tissue and eye, or by a separate agreement with another tissue and/or eye bank outside the OPO, chosen by the CAH. The CAH may continue current successful direct arrangements with tissue and eye banks as long as the direct arrangement does not interfere with organ procurement. Surveyors will verify that the CAH has an agreement with at least one tissue bank and one eye bank that specifies criteria for referral of all individuals who have died in the CAH. The agreement must also acknowledge that it is the OPO's responsibility to determine medical suitability for tissue and eye donation, unless the CAH has an alternative agreement with a different tissue and/or eye bank.	Review of following document(s): Binder – CAH Organ, Tissue and Eye Procurement Policies and Procedures Binder – CAH Agreements and Contracts, esp. agreements with at least one tissue bank and one eye bank Review of closed medical records of patients who have died in the CAH in the past six months Interviews with staff

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C347	(c) Standard: Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its options to either donate or not donate organs, tissues, or eyes. The individual designated by the CAH to initiate the request to the family must be a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation:	It is the responsibility of the OPO to screen for medical suitability in order to select potential donors. Once the OPO has selected a potential donor, that person's family must be informed of the family's donation options. Ideally, the OPO and the CAH will decide together how and by whom the family will be approached. The individual designated by the CAH to initiate the request to the family must be a designated requestor. A "designated requestor" is defined as a CAH-designated individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community. If possible, the OPO representative and a designated requestor should approach the family together. The CAH must ensure that any "designated requestor" for organs, tissues or eyes has completed a training course either offered or approved by the OPO, which addresses methodology for approaching potential donor families.	Review of following document(s): Binder – CAH Organ, Tissue and Eye Procurement Policies and Procedures Binder – CAH Agreements and Contracts, esp. the CAH-OPO agreement Review of closed medical records of patients who have died in the CAH in the past six months Interviews with staff and family members of deceased patients
C348	(d) <u>Standard</u> : Encourages discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;	Using discretion does not mean a judgement can be made by the hospital that certain families should not be approached about donation. CAHs should approach the family with the belief that a donation is possible and should take steps to ensure the family is treated with respect and care. The CAH's staff perception that a family's grief, race, ethnicity, religion, or socioeconomic background would prevent donation should never be used as a reason not to approach a family. All potential donor families must be approached and informed of their donation rights.	Review of following document(s): Binder – CAH Organ, Tissue and Eye Procurement Policies and Procedures Binder – CAH Agreements and Contracts, esp. the CAH-OPO agreement Review of closed medical records of patients who have died in the CAH in the past six months CAH in-service training records or logs Complaint logs Interviews with staff and family members of deceased patients

TAG	REGULATION	ELEMENTS TO CONSIDER	EVIDENCE/SURVEYORS' FOCUS
C349	(e) Standard: Ensure that the CAH works cooperatively with the designated OPO, tissue bank, and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place; and (f) For purposes of these standards the term "Organ" means a human kidney, liver, heart, lung or pancreas.	Appropriate staff, including all patient care staff, must be trained regarding donation issues and how to work with the OPO, tissue bank and eye bank. Those CAH staff who may have to contact or work with the OPO, tissue bank and eye bank staff, must have appropriate training on donation issues including their duties and roles. The training program must be developed in cooperation with the OPO, tissue bank and eye bank, and should include, at a minimum: (a) Consent process; (b) importance of using discretion and sensitivity when approaching families; (c) role of the designated requestor; (d) transplantation and donation, including pediatrics, if appropriate; Quality improvement activities; and (e) role of the organ procurement organization. Training should be conducted with new employees annually, whenever there are policy/procedure changes, or when problems are determined through the CAH's QA program. The CAH must cooperate with OPOs, tissue banks and eye banks in regularly/periodically reviewing death records. This means that a CAH must develop policies and procedures which permit the OPO, tissue bank and eye bank access to death record information that will allow the OPO, tissue bank and eye bank to assess the CAH's donor potential, ensure that all deaths or imminent deaths are being referred to the OPO in a timely manner, and identify areas where the CAH, OPO, tissue bank and eye bank staff performance might be improved. The policies must address how patient confidentiality will be maintained during the review process. The CAH must have policies and procedures, developed in cooperation with the OPO, that ensure that potential donors are maintained in a manner that maintain the viability of their organs. The CAH must have policies in place to ensure that potential donors are identified and declared dead within an acceptable time frame by an appropriate practitioner.	Review of following document(s): Binder - CAH Organ, Tissue and Eye Procurement Policies and Procedures Binder - CAH Agreements and Contracts, esp. the CAH-OPO agreement Review of closed medical records of patients who have died in the CAH in the past six months Interviews with staff

Special requirements for CAH provides of long-term care services (swing-bed)

TAG	REGULATION	ELEMENTS TO CONSIDER
C350	§485.645 Special requirements for CAH provides of long-term care services (swing-bed). A CAH must meet the following requirements in order to be granted an approval from CMS to provide post-hospital SNF care, and to be paid for SNF-level services, in accordance with paragraph (b) of this section.	The swing-bed concept allows a CAH to use their beds interchangeably for either acute- care or post-acute care. A "swing-bed" is a change in reimbursement status. The patient swings from receiving acute-care services and reimbursement to receiving skilled nursing (SNF) services and reimbursement. Medicare allows a CAH to operate swing-beds through the issuance of a "swing-bed approval." If the facility fails to meet the swing-bed requirements, and the facility does not develop and implement an accepted plan of correction, the facility loses the approval to operate swing-beds and receive swing-bed reimbursement. The facility does not go on a termination track. If the CAH continues to meet the CoP for the provider type, it continues to operate but loses swing-bed approval. Swing-beds need not be located in a special section of the CAH. The patient need not change locations in the facility merely because his/her status changes unless the facility requires it. The change in status from acute care to swing-bed status can occur within one facility or the patient can be transferred from another facility for swing-bed admission. There must be discharge orders from acute care services, appropriate progress notes, discharge summary, and subsequent admission orders to swing-bed status regardless of whether the patient stays in the same facility or transfers to another facility. If the patient does not change facilities, the same chart can be utilized but the swing-bed section of the chart must be separate with appropriate admission orders, progress notes, and supporting documents. There is no length of stay restriction for any CAH swing-bed patient. There is no Medicare requirement to place a swing-bed patient in a nursing home and there are no requirements for transfer agreements between CAHs and nursing homes. Medicare reimbursement requires a 3-day qualifying stay in any hospital or CAH prior to admission to a swing-bed. The swing-bed stay must fall within the same spell of illness as the qualifying stay. This requ

TAG	REGULATION	ELEMENTS TO CONSIDER
C351	(a) Eligibility. A CAH must meet the following eligibility requirements –	
	(1) The facility has been certified as a CAH by CMS under §485.606(b) of this subpart; and	
	(2) The facility provides not more than 25 inpatient beds, and the number of beds used at any time for acute care inpatient services does not exceed 15 beds. Any bed of a unit of the facility that is licensed as a distinct-part SNF at the time the facility applies to the State for designation as a CAH is not counted under paragraph (a) of this section.	
C352	(b) Facilities participating as rural primary care hospitals (RPCHs) on September 30, 1997. These facilities must meet the following requirements –	Not applicable in Nevada.
	(1) Notwithstanding paragraph (a) of this section, a CAH that participated in Medicare as a RPCH on September 30, 1997, and on that date had in effect an approval from CMS to use its inpatient facilities to provide post-hospital SNF care may continue in that status under the same terms, conditions and limitations that were applicable at the time these approvals were granted.	
	(2) A CAH that was granted swing-bed approval under paragraph (b)(1) of this section may request that its application to be a CAH and a swing-bed provider be reevaluated under paragraph (a) of this section. If this request is approved the approval is effective not earlier than October 1, 1997. As of the date of approval, the CAH no longer has any status under paragraph (b)(1) of this section, and may not request reinstatement under paragraph (b)(1) of this section.	
C355	(c) <u>Payment</u> . Payment for inpatient RCPH services to a CAH that has qualified as a CAH under the provisions in paragraph (a) of this section is made in accordance with §413.70 of this chapter. Payment for post-hospital SNF-level care of services is made in accordance with the payment provisions in §413.114 of this chapter.	

TAG	REGULATION	ELEMENTS TO CONSIDER
C360	(d) <u>SNF services.</u> The CAH is substantially in compliance with the following SNF requirements contained in Subpart B of part 483 of this chapter. (1) Resident rights (§483.10(b)(3) through (b)(6), (d), (e), (h), (j)(i)(vii) and (viii), (1), and (m) of this chapter); (2) Admission, transfer, and discharge rights (§483.12(a) of this chapter); (3) Resident behavior and facility practices (§483.13 of this chapter); (4) Patient activities (§483.15(f) of this chapter), except that the services may be directed either by a qualified professional meeting the requirement of §485.15(f)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy; (5) Social services ((§483.15(g) of this chapter); (6) Comprehensive assessment, comprehensive care plan, and discharge planning (§483.20(b), (d), and (e) of this chapter); (7) Specialized rehabilitative services (§483.45 of this chapter); (8) Dental services (§483.55 of this chapter); (9) Nutrition (§483.25(i) of this chapter).	Most hospitals applying for CAH status probably do not meet these requirements at present. The following requirements must be met for approval as a CAH.
C361	§483.10 Residents rights. The resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility. A facility must protect and promote the rights of each resident, including each of the following: (b) Notice of rights and services. (3) The resident has the right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition.	The intent of this requirement is to assure that each resident knows his or her rights and responsibilities and that the facility communicates this information prior to or upon admission, during the resident's stay, and when the facility's rules changes. A facility must promote the exercise of rights for all residents, including those who face barriers such as communication problems, hearing problems and cognition limits. These rights include the resident's right to: (a) Be informed about what rights and responsibilities the resident has (§483.10(b)(3 through 6)); (b) choose a physician (§483.10(d)(1)); (c) participate in decisions about treatment and care planning (§483.10(d)(3)); (d) have privacy and confidentiality (§483.10(e)); (e) work or not work (§483.10(h)); (f) have privacy in sending and receiving mail (§483.10(I)); (g) visit and be visited by others from outside the facility (§483.10(j)(1)(vii and viii)); (h) retain and use personal possessions (§483.10(I)); (i) share a room with a spouse (§483.10(m)). "Total health status" includes functional status, medical care, nursing care, nutritional status, rehabilitation and restorative potential, activities potential, cognitive status, oral health status must be presented in language that the resident can understand. Communicating with the resident in language that the resident can understand includes minimizing the use of technical words, providing interpreters for non-English speaking residents, using sign language when needed, or other interventions, as appropriate.

TAG	REGULATION	ELEMENTS TO CONSIDER
C362	(4) The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph (8) of this	"Treatment" is defined as care provided for purposes of maintaining/restoring health, improving functional level, or relieving symptoms.
	section; and	"Experimental research" is defined as development and testing of clinical treatments, such as an investigational drug or therapy that involve treatment and/or control groups. For example, a clinical trial of an investigational drug would be experimental research.
		"Advance directive" means a written instruction, such as living will or durable power of attorney for health care, recognized under state law, relating to the provisions of health care when the individual is incapacitated.
		A resident who has the capacity to make a health care decision and who withholds consent to treatment or makes an explicit refusal of treatment either directly or through an advance directive, may not be treated against his/her wishes. The resident has the right to refuse to participate in experimental research. A resident being considered for participation in experimental research must be fully informed of the nature of the experiment and understand the possible consequences of participating. The opportunity to refuse to participate in experimental research must occur prior to the start of the research. Aggregated resident statistics that do not identify individual residents may be used for studies without obtaining resident permission.
		Note: §483.10(b)(8) The facility must comply with the requirements specified in subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. These requirements include provisions to inform and provide written information to all adult residents concerning the right to accept or refuse medical or surgical treatment and, at the individual's option, formulate an advance directive. This includes a written description of the facility's policies to implement advance directives and applicable State law. Facilities are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met. If an adult individual is incapacitated at the time of admission and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, facility may give advance directive information to the individual's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law. The facility is not relieved of its obligation to provide this information to the individual once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.

TAG	REGULATION	ELEMENTS TO CONSIDER
C362 continued	(4) The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph (8) of this section; and	This provision applies to residents admitted on or after December 1, 1991. The regulation at 42 CFR §489.102 specifies that at the time of admission of an adult resident, the facility must: (a) Maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care; (b) provide written information concerning his or her rights under Nevada law (whether statutory or recognized by the courts of the State) to make decisions concerning medical care, including the right to accept or refuse medical or surgical treatment, and the right to formulate advance directives; (c) document in the resident's medical record whether or not the individual has executed an advance directive; (d) not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive; (e) ensure compliance with requirements of State law regarding advance directives; Provide for educating staff regarding the facility's policies and procedures on advance directives; and (f) provide for community education regarding issues concerning advance directives. The facility is not required to provide care that conflicts with an advance directive. In addition, the facility is also not required to implement an advance directive, and state law allows the provider to conscientiously object. The sum total of the community education efforts must include a summary of the state law, the rights of residents to formulate advance directives, and the facility's implementation policies regarding advance directives. Video and audiotapes may be used in conducting the community education effort. Individual education programs do not have to address all the requirements if it would be inappropriate for a particular audience.
C363	 (5) The facility must – (i) Inform each resident who is entitled to Medicaid benefits, in writing, at the time of admission to the nursing facility or, when the resident becomes eligible for Medicaid of – (A) The items and services that are included in nursing facility services under the State plan and for which the resident may not be charged; (B) Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and 	If Medicare or Medicaid does not make payment for services, the provider must fully inform the resident of any related charges both at the time of admission and prior to the time that changes will occur in their bills. Listed below are general categories and examples of items and services that the facility may charge to resident funds, if they are requested and agreed to by a resident. Telephone; Television/radio for personal use; Personal comfort items including smoking materials, notions, novelties, and confection; Cosmetic and grooming items and services in excess of those for which payment is made; Personal clothing; Personal reading matter; Gifts purchased on behalf of a resident; Flowers and plants; Social events and entertainment offered outside the scope of the activities program; Non-covered special care services such as privately hired nurses or aides; Private room, except when therapeutically required, for example,
	 (ii) Inform each resident when changes are made to the items and services specified in paragraphs (5)(i)(A) and (B) of this section. (6) The facility must inform each resident before, or at the time of admission, and 	isolation for infection control; and/or Specially prepared or alternative food requested. Are residents told in advance when changes will occur in their bills? Does the hospital inform the resident of services and related changes?
	periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare or by the facility's's per diem rate.	Are patients advised on admission that certain services may not be covered and that they are personally responsible?

TAG	REGULATION	ELEMENTS TO CONSIDER
C364	(d) Free Choice – The resident has the right to – (1) Choose a personal attending physician;	The right to choose a personal physician does not mean that the physician must serve the resident. If the physician of the resident's choosing fails to fulfill a given requirement, such as frequency of physician visits, the facility will have the right, after informing the resident, to seek alternate physician participation to assure provision of appropriate and adequate care and treatment. A facility may not place barriers in the way of residents choosing their own physician. If a resident does not have a physician, or if the resident's physician becomes unable or unwilling to continue providing care to the resident, the facility must assist the resident in exercising his/her choice in finding another physician. A resident can choose his/her own physician, but cannot have a physician who does not have swing-bed admitting privileges. The requirement for free choice is met if a resident is allowed to choose a personal physician from among those who have practice privileges.
C365	(2) Be fully informed in advance about the care and treatment and of any changes in that care or treatment that may affect the resident's well-being; and	"Informed in advance" means that the resident receives information necessary to make a health care decision. The information should include his/her medical condition, changes in his/her medical condition, the benefits and reasonable risks of the recommended treatment, and reasonable alternatives. If there are any financial costs to the resident in the treatment options, they should be disclosed in advance and in writing to the resident prior to his/her decision. Do patients receive information about their medical condition and changes in medical condition, about the benefits and reasonable risks of the treatment, and about reasonable available alternatives?
C366	(3) Unless adjudged incompetent or otherwise found to be incapacitated under the laws of the State, participate in planning care and treatment or changes in care and treatment.	"Participates in planning care and treatment" means that the resident is afforded the opportunity to select from alternative treatments, to the level of his ability to understand. This applies both to initial decisions about care and treatment and to decisions about changes in care and treatment. The resident has the right to participate in care planning and to refuse treatment. Note: Incompetency is a legal <u>not</u> a medical determination. Residents are involved in decisions about care and treatment. If there are conflicts between a resident's right and the resident's health or safety, the facility must attempt to accommodate both the exercise of the resident's rights and the resident's health, including exploration of care alternatives through a thorough care planning process in which the resident participates.

TAG	REGULATION	ELEMENTS TO CONSIDER
C367	 (e) Privacy and confidentiality. The resident has the right to personal privacy and confidentiality for his or her personal and clinical records. (1) Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident; (2) Except as provided in paragraph (e)(3) of this section, the resident may approve or refuse the release of personal and clinical records to any individual outside the facility; (3) The resident's right to refuse release of personal and clinical records does not apply when – 	"Right to personal privacy" means that the resident has the right to privacy with whomever the resident wishes to be private and that this privacy should include both visual and auditory privacy. Private space may be created flexibly and need not be dedicated solely for visitation purposes. For example, privacy for visitation or meetings might be arranged by using a dining area between meals, a vacant chapel, office or room; or an activities area when activities are not in progress. Arrangements for private space could be accomplished through cooperation between the facility's administration and resident or family groups so that private space is provided for those requesting it without infringement on the rights of other residents.
	(i) The resident is transferred to another health care institution; or (ii) Record release is required by law.	Facility staff must examine and treat residents in a manner that maintains the privacy of their bodies. A resident must be granted privacy when going to the bathroom and in other activities of personal hygiene. If an individual requires assistance, authorized staff should respect the individual's need for privacy. Only authorized staff directly involved in treatment should be present when treatments are given. People not involved in the care of the individual should not be present without the individual's consent while he/she is being examined or treated. Staff should pull privacy curtains, close doors, or otherwise remove residents from public view and provide clothing or draping to prevent unnecessary exposure of body parts during the provision of personal care and services.
C368	 (h) Work. The resident has the right to – (1) Refuse to perform services for the facility; (2) Perform services for the facility, if he or she chooses, when (i) The facility has documented the need or desire for work in the plan of care; (ii) The plan specifies the nature of the services performed and whether the services are voluntary or paid; (iii) Compensation for paid services is at or above prevailing rates; and (iv) The resident agrees to the work arrangement described in the plan of care. 	All resident work, whether of a voluntary or paid nature, must be part of the plan of care. A resident's desire for work is subject to medical appropriateness. As part of the plan of care, the resident must agree to a therapeutic work assignment. The resident also has the right to refuse such treatment at any time that he or she wishes. At the time of development or review of the plan, voluntary or paid work can be negotiated. The "prevailing rate" is the wage paid to workers in the community surrounding the facility for the same type, quality, and quantity of work requiring comparable skills.
C369	 (i) Mail. The resident has the right to privacy in written communications, including the right to – (1) Send and promptly receive mail that is unopened; and (2) Have access to stationery, postage, and writing implements at the resident's own expense. 	"Promptly" means delivery of mail or other materials to the resident within 24 hours of delivery by the postal service (including a post office box) and delivery of outgoing mail to the postal service within 24 hours of regularly scheduled postal delivery and pickup service.

TAG	REGULATION	ELEMENTS TO CONSIDER
C370	 (j) Access and Visitation Rights. (1) The resident has the right and the facility must provide immediate access to any resident by the following: (i) Any representative of the Secretary; (vii) Subject to the resident's right to deny or withdraw consent at any time, immediate family or other relatives of the resident; and (viii) Subject to reasonable restrictions and the resident's right to deny or withdraw consent at any time, others who are visiting with the consent of the resident. 	Existing visiting hours limitations may conflict with this provision. Immediate family or other relatives are not subject to visiting hour limitations or other restrictions not imposed by the resident. Non-family visitors are also granted "immediate access" to the resident. An individual or representative of an agency that provides health, social, legal or other services to the resident has the right of "reasonable access" to the resident. The facility may set reasonable hours for visitation. If it would violate the rights of a roommate to have visitors in the resident's room, the facility must establish alternate areas in the facility for visiting. These areas could include the chapel, a suitable office area, a dining room, or a porch or patio area.
C371	(1) <u>Personal Property.</u> The resident has the right to retain and use personal possessions, including some furnishings, and appropriate clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.	The intent of this regulation is to encourage residents to bring personal possessions into the facility, as space, safety considerations and fire code permits. All residents' possessions must be treated with respect and safeguarded. The facility has the right to limit personal property due to space limitations in the facility or for safety considerations. Surveyors will check to see that the resident has the right to retain and use personal possessions, including some furnishings, and appropriate clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents. All residents' possessions, regardless of their apparent value to others, are treated with respect, for what they are and for what they may represent to the resident.
C372	(m) <u>Married couples.</u> The resident has the right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.	The right of residents who are married to each other to share a room does not give a resident the right, or the facility the responsibility, to compel another resident to relocate to accommodate a spouse. When a room is available for a married couple to share, the facility must permit them to share it if they choose.
C373	§483.12 Admission, transfer and discharge rights. (a) Transfer and discharge: (1) Definition: Transfer and discharge includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plan or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility.	The intent of the regulation on transfer and discharge provisions is to significantly restrict a facility's ability to transfer or discharge a resident once that resident has been admitted to the facility to prevent dumping of high care or difficult residents. This requirement applies to transfer or discharges that are initiated by the facility, not by the resident. To demonstrate that any of these events have occurred, the law requires documentation in the resident's clinical record.

TAG	REGULATION	ELEMENTS TO CONSIDER
C374	(2) <u>Transfer and discharge requirements.</u> The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless – (i) The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility;	If transfer is due to a significant change in the resident's condition, the facility must conduct the appropriate assessment, prior to any transfer or discharge to determine if a new care plan would allow the facility to meet the resident's needs. If the significant change in the resident's condition is an emergency, immediate transfer should be arranged.
	(ii) The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility;	Did a physician document the record if residents were transferred because the health of individuals in the facility is endangered?
	(iii) The safety of individuals in the facility is endangered;(iv) The health of individuals in the facility would otherwise be endangered;	Do the records of residents transferred/discharged due to safety reasons reflect the process by which the facility concluded that in each instance transfer or discharge was necessary? If so, determine differences between these residents and those who were transferred or discharged.
	(v) The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge a resident only allowable charges under Medicaid; or	nuistoried of discharged.
	(vi) The facility ceases to operate.	
C376	(3) <u>Documentation</u> . When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (a)(2)(i) through (v) of this section, the resident's clinical record must be documented. The documentation must be made by –	A physician extender may complete documentation of the transfer/discharge unless prohibited by State law or facility policy.
	(i) The resident's physician when transfer or discharge is necessary under paragraph (a)(2)(i) or paragraph (a)(2)(ii) of this section; and	
	(ii) A physician when transfer or discharge is necessary under paragraph (a)(2)(iv) of this section.	
C377	(4) <u>Notice before transfer</u> . Before a facility transfers or discharges a resident, the facility must –	
	(i) Notify the resident and, if known, a family member or legal representative of the resident of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand.	
	(ii) Record the reasons in the resident's clinical record; and	
	(iii) Include in the notice the items described in paragraph (a)(6) of this section.	

TAG	REGULATION	ELEMENTS TO CONSIDER
C378	(5) <u>Timing of the notice</u> .	
	(i) Except when specified in paragraph (a)(5)(ii) of this section, the notice of transfer or discharge required under paragraph (a)(4) of this section must be made by the facility at least 30 days before the resident is transferred or discharged.	
	(ii) Notice may be made as soon as practicable before transfer or discharge when	
	(a) The safety of individuals in the facility would be endangered under paragraph (a)(2)(iii) of this section.	
	(b) The health of individuals in the facility would be endangered, under paragraph (a)(2)(iv) of this section;	
	(c) The resident's health improves sufficiently to allow a more immediate transfer or discharge under paragraph (a)(2)(ii) of this section;	
	(d) An immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph (a)(2)(i) of this section; or	
	(e) A resident has not resided in the facility for 30 days.	
C379	(6) <u>Contents of the notice</u> . The written notice specified in paragraph (a)(4) of this section must include the following:	
	(i) The reason for transfer or discharge;	
	(ii) The effective date of transfer or discharge;	
	(iii) The location to which the resident is transferred or discharged;(iv) A statement that the resident has the right to appeal the action to the State;	
	(v) The name, address and telephone number of the State long term care ombudsman;	
	(vi) For nursing facility residents with developmental disabilities, the mailing address and telephone number of the agency responsible for the protection and advocacy of developmentally disabled individuals established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act; and	
	(vii) For nursing facility residents who are mentally ill, the mailing address and telephone number of the agency responsible for the protection and advocacy of mentally ill individuals established under the Protection and Advocacy for Mentally ill Individuals Act.	

TAG	REGULATION	ELEMENTS TO CONSIDER
C380	(7) Orientation for transfer or discharge. A facility must provide sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility.	"Sufficient preparation" means the facility informs the resident where he or she is going and assures safe transportation. The facility should actively involve the resident and the resident's family in selecting the new residence. Some examples of orientation may include trial visits by the resident to a new location; working with family; and orienting staff in the receiving facility to the resident's daily patterns. The facility informs the resident where he or she is going and takes steps under its control to assure safe transportation. The facility should actively involve, to the extent possible, the resident and the resident's family in selecting the new residence.
C381	§483.13 Resident behavior and facility practices. (a) Restraints. The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms.	The intent of this requirement is for each person to reach his/her highest practicable well being in an environment that prohibits the use of restraints for discipline or convenience and limits restraint use to circumstances in which the resident has medical symptoms that warrant the use of restraints. "Physical restraints" are defined as any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily and that restricts freedom of movement or normal access to one's body. "Chemical Restraint" is defined as a psychopharmacologic drug that is used for discipline or convenience and not required to treat medical symptoms. "Discipline" is defined as any action taken by the facility for the purpose of punishing or penalizing residents. "Convenience" is defined as any action taken by the facility to control resident behavior or maintain residents with a lesser amount of effort by the facility and not in the resident's best interest. Medical symptoms that would warrant the use of restraints should be reflected in the comprehensive assessment and care planning. The facility must engage in a systematic and gradual process toward reducing restraints (e.g., gradually increasing the time for ambulation and muscle strengthening activities).

TAG	REGULATION	ELEMENTS TO CONSIDER
C382	C382 (b) Abuse. The resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion.	The intent of this regulation is to assure that each resident is free from abuse, corporal punishment, and involuntary seclusion. The facility is responsible for preventing abuse, but also for those practices and omissions, neglect and misappropriation of property, which if left unchecked, lead to abuse. Residents must not be subjected to abuse by anyone, including, but not limited to, facility staff, other residents, consultants or volunteers, staff of other agencies serving the individual, family members or legal guardians, friends, or other individuals. "Abuse" is defined as the willful inflection of injury, unreasonable confinement,
		intimidation, or punishment with resulting physical harm or pain or mental anguish, or deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. This presumes that instances of abuse of all residents, even those in a coma, cause physical harm, or pain or mental anguish.
		"Verbal abuse" is defined as any use of oral, written or gestured language that willfully includes disparaging and derogatory terms to residents or their families, or within their hearing distance, regardless of their age, ability to comprehend, or disability. Examples of verbal abuse include, but are not limited to: threats of harm; saying things to frighten a resident, such as telling a resident that she will never be able to see her family again.
		"Sexual abuse" includes, but is not limited to, sexual harassment, sexual coercion, or sexual assault.
		"Physical abuse" includes hitting, slapping, pinching and kicking. It also includes controlling behavior through corporal punishment.
		"Mental abuse" includes, but is not limited to, humiliation, harassment, threats of punishment or deprivation.
		"Involuntary seclusion" is defined as separation of a resident from other residents or from his or her room or confinement to his or her room (with or without roommates) against the resident's will, or the will of the resident's legal representative. Emergency or short term monitored separation from other residents will not be considered involuntary seclusion and may be permitted if used for a limited period of time as a therapeutic intervention to reduce agitation until professional staff can develop a plan of care to meet the resident's needs.

TAG	REGULATION	ELEMENTS TO CONSIDER
C383	(c) <u>Staff treatment of residents.</u> The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property.	The intent of this regulation is to assure that the facility has in place an effective system that prevents mistreatment, neglect and abuse of residents, and misappropriation of resident's property.
	(1) The facility must – (i) Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;	"Neglect" means failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness. "Misappropriation of resident's property" is defined as the patterned or deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a resident's belongings or money without the resident's consent.

TAG	REGULATION	ELEMENTS TO CONSIDER
C384	 (ii) Not employ individuals who have been – (A) Found guilty of abusing, neglecting, or mistreating residents by a court of law; or (B) Have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property; and (iii) Report any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff to the State nurse aide registry or licensing authorities. (2) The facility must ensure that all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source and misappropriation of resident property are reported immediately to the officials in accordance with State law through established procedures (including the State survey and certification agency). (3) The facility must have evidence that all alleged violations are thoroughly investigated, and must prevent further potential abuse while the investigation is in progress. (4) The results of all investigations must be reported to the administrator or his designed representative and to other officials in accordance with Sate law (including to the State survey and certification agency) within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken. 	The intent of this regulation is to prevent employment of individuals who have been convicted of abusing, neglecting, or mistreating individuals in a health care related setting. In addition to inquiry of the State nurse aide registry or other licensing authorities, the facility should check all staff references and make reasonable efforts to uncover information about any past criminal prosecutions. "Found guiltyby a court of law" applies to situations where the defendant pleads guilty, is found guilty, or pleads nolo contendere. "Finding" is defined as a determination made by the State that validates allegations of abuse, neglect, mistreatment of residents or misappropriation of their property. Any facility staff found guilty of neglect, abuse, or mistreating residents or misappropriation of property by a court of law must have his or her name entered into the nurse aide registry, or reported to the licensing authority, as appropriate. Surveyors will evaluate whether a facility does a thorough investigation of the past histories of individuals they are considering hiring. In addition to inquiry of the State nurse aide registry or other licensing authorities, the facility will check all references and make reasonable efforts to uncover information about any past criminal prosecutions. An aide or other facility staff found guilty of neglect, abuse, or mistreating residents or misappropriation of property by a court of law, will have his or her name entered into the nurse aide registry, or reported to the licensing authority, if applicable. Further, if actions by a court of law against an employee are such that they indicate that the individual is unsuited to work in a nursing home (e.g., felony conviction of child abuse, sexual assault, or assault with a deadly weapon), the hospital will report that individual to the nurse aide registry (if a nurse aide) or to the State licensing authority (if a licensed staff member). Such a determination is not limited to mistreatment, neglect and abuse of residents

TAG	REGULATION	ELEMENTS TO CONSIDER
C385	§483.15 Quality of Life. A facility must care for its residents in a manner and in an environment that promotes maintenance or enhancement of each resident's quality of life.	A "recognized accrediting body" refers to those organizations or associations recognized as such by certified therapeutic recreation specialists or certified activity professionals or registered occupational therapists.
	(f) Activities. (1) The facility must provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident.	The activities program should be multi-faceted and reflect individual resident's needs on their care plan. Activities can occur at anytime and are not limited to formal activities being provided by activity staff. Others involved may be any facility staff, volunteers, and visitors.
	(2) The activities program must be directed by a qualified professional who – (i) Is a qualified therapeutic recreation specialist or an activities professional who –	In a Critical Access Hospital, the services at §483.15(f) may be directed either by a qualified professional meeting the requirements of §483.15(f)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other
	(A) Is licensed or registered, if applicable, by the State in which practicing; and	professional with experience or education in recreational therapy.
	(B) Is eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or	Surveyors will determine whether there is an activities program that: (a) Provides stimulation or solace; (b) promotes physical, cognitive and/or emotional health; (c) enhances to the extent practicable, each resident's physical and mental status; and (d) promote each resident's self-respect by providing activities that support self-expression
	(ii) Has 2 years of experience in a social or recreational program within the last 5 years, 1 of which was full-time in a patient activities program in a health care setting; or	and choice.
	(iii) Is a qualified occupational therapist or occupational therapy assistant; or	Activities can occur at anytime and are not limited to formal activities being provided by activity staff. Others involved may be any facility staff, volunteers, and visitors.
	(iv) Has completed a training course approved by the State.	

TAG	REGULATION	ELEMENTS TO CONSIDER
C386	(g) <u>Social Services</u> . (1) The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.	The intent of this regulation is to assure that all facilities provide for the medically-related social services needs of each resident. This requirement specifies that facilities aggressively identify the need for medically-related social services, and pursue the provision of these services. A qualified social worker need not personally provide all of these services. It is the responsibility of the facility to identify the medically-related social service needs of the resident and assure that the needs are met by the appropriate discipline.
		Surveyors will determine whether the facility provides for the medically-related social services needs of each resident. Does the facility aggressively identify the need for medically-related social services, and pursue the provision of these services?
		"Medically-related social services" means services provided by the facility's staff to assist residents in maintaining or improving their ability to manage their everyday physical, mental, and psychosocial needs. These services might include, for example: Making arrangements for obtaining needed adaptive equipment, clothing, and personal items; Maintaining contact with family (with resident's permission) to report on changes in health, current goals, discharge planning, and encouragement to participate in care planning; Assisting staff to inform residents and those they designate about the resident's health status and health care choices and their ramifications; Making referrals and obtaining services from outside entities (e.g., talking books, absentee ballots, community wheelchair transportation); Assisting residents with financial and legal matters (e.g., applying for pensions, referrals to lawyers, referrals to funeral homes for preplanning arrangements); Building relationships between residents and staff and teaching staff how to understand and support residents' individual needs; Promoting actions by staff that maintain or enhance each resident's dignity in full recognition of each resident's individuality; and Assisting residents to determine how they would like to make decisions about their health care, and whether or not they would like anyone else to be involved in those decisions.
		Factors with a potentially negative effect on physical, mental, and psychosocial well-being include an unmet need for: Dental/denture care; Podiatric care; Eye care; Hearing services; Equipment for mobility or assistive eating devices; and Need for home-like environment, control, dignity, privacy.

TAG	REGULATION	ELEMENTS TO CONSIDER
C386 continued	(g) Social Services. (1) The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.	Where needed services are not covered by the Medicaid State Plan, the facility still attempts to obtain these services. For example, if a resident requires transportation services that are not covered under a Medicaid State Plan, the facility is required to arrange these services. This could be achieved, for example, through obtaining volunteer assistance. Types of conditions to which the facility should respond with social services by staff or referral include: Lack of an effective family/social support system; Behavioral symptoms; If a resident with dementia strikes out at another resident, the facility should evaluate the resident's behavior; Presence of a chronic disabling medical or psychological condition (e.g., multiple schizophrenia); Depression; Chronic or acute pain; Difficulty with personal interaction and socialization skills; Presence of legal or financial problems; Abuse of alcohol or other drugs; Inability to cope with loss of function; Need for emotional support;
		 Changes in family relationships, living arrangements, and/or resident's condition or functioning; and A physical or chemical restraint.

TAG	REGULATION	ELEMENTS TO CONSIDER
C388	§483.20 Resident assessment. The facility must conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity. (b) Comprehensive assessment. (1) The facility must make a comprehensive assessment of a resident's needs which — (i) Is based on a uniform data set specified by the Secretary and uses an instrument that is specified by the State and approved by the Secretary; and (ii) Describes the resident's capability to perform daily life functions and significant impairments in functional capacity. (2) The comprehensive assessment must include at least the following information — (i) Medically defined conditions and prior medical history; (ii) Medical status measurement; (iii) Physical and mental functional status; (iv) Sensory and physical impairments; (v) Nutritional status and requirements; (vi) Special treatments or procedures; (vii) Mental and psychosocial status; (viii) Discharge potential; (ix) Dental condition; (x) Activities potential; (xi) Rehabilitation potential; (xii) Cognitive status; and (xiii) Drug therapy.	The intent of this regulation is to provide the facility with ongoing assessment information necessary to develop a care plan, to provide the appropriate care and services for each resident, and to modify the care plan and care/services based on the resident's status. The facility is expected to use resident observation and communication as the primary source of information when completing the assessment. In addition to direct observation and communication with the resident, the facility should use a variety of other sources, including communication with licensed and nonlicensed staff members on all shifts and may include discussions with the resident's MD/DO, family members, or outside consultants and review of the resident's record. Note: CMS will consider CAH facilities that meet all but the Minimum Data Set (MDS) SNF requirements to be in substantial compliance with the CAH swing bed regulations. CMS still requires CAHs to complete a resident assessment and a comprehensive care plan for each SNF patient and document the assessment in the medical record. However, CMS will no longer require CAHs to use the MDS instrument for the residential assessments.
C389	§483.20(b)(2) When required. Subject to the timeframes prescribed in §413.343(b) of this chapter, a facility must conduct a comprehensive assessment of a resident in accordance with the timeframes specified in paragraphs (b)(2)(i) through (iii) of this section. The timeframes prescribed in §413.343(b) of this chapter do not apply to CAHs. (i) Within 14 calendar days after admission, excluding readmissions in which there is no significant change in the resident's physical or mental condition. (For purposes of this section, "readmission" means a return to the facility following a temporary absence for hospitalization or for therapeutic leave.)	The intent of this regulation is to assess residents in a timely manner. Patients are assessed not later than 14 days after admission. "Admission" to be the facility is defined as an initial stay or a return stay (not a readmission) in the facility. A return stay applies to those residents who are discharged without expectation that they will return to the facility, but who do return to the facility. A "readmission" is an expected return to the facility following a temporary absence for hospitalization, off-site visit or therapeutic leave. A resident who is readmitted and for whom there is a prior RAI on file does not require a new assessment unless a significant change in status has occurred (see below), and should remain on the same schedule as if there had been no temporary absence.

TAG	REGULATION	ELEMENTS TO CONSIDER
C390	§483.20(b)(2)(ii) Within 14 calendar days after the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition. (For purposes of this section, a "significant change" means a major decline or improvement in the resident's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the resident's health status, and requires inter-disciplinary review or revision of the care plan, or both.) (iii) Not less often than once every 12 months.	If a resident experiences a significant change in status, the next annual assessment is not due until 365 days after the significant change assessment. Facilities may correct errors on the MDS per CMS policy within 7 days of its completion. "Promptly" means that once it is determined that the resident's change in status is significant or likely to be permanent, a full assessment must be completed within 14 days of this determination. A "significant change" may include, but is not limited to, any of the following, or may be determined by a physician's decision if uncertainty exists. Deterioration in two of more activities of daily living (ADLs), or any combination of deterioration in two of more areas of ADLs, communication, or cognitive abilities that appear permanent. For example, pronounced deterioration in function and communication following a stroke. Loss of ability to ambulate freely or to use hands to grasp small objects to feed or groom oneself, such as spoon, toothbrush, or comb. Temporary loss of ability, such as during an acute illness, is not included. Deterioration in behavior or mood, to the point where daily problems arise or relationships have become problematic and staff conclude that these changes in the resident's psychosocial status are not likely to improve without staff intervention. Deterioration in a resident's health status, where this change places the resident's life in danger (e.g., stroke, heart disease, metastatic cancer); where the change is associated with a serious clinical complication (e.g., initial development of a stage III pressure sore, prolonged delirious state, or recurrent decline in level of consciousness); or change that is associated with an initial diagnosis of a condition that is likely to affect the resident's physical, mental, or psychosocial well-being over a prolonged period of time (e.g., Alzheimer's disease or diabetes); or the onset of significant, unplanned weight loss (5% in the last 30 days, 10% in the last 180 days).

TAG	REGULATION	ELEMENTS TO CONSIDER
C395	(d) Comprehensive care plans. (1) The facility must develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing and mental and psychosocial needs that are identified in the comprehensive assessment. The care plan must describe the following — (i) The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psycho-social well-being as required under §483.25; and (ii) Any services that would otherwise be required under §483.25 but are not provided due to the resident's exercise of rights under §483.10, including the right to refuse treatment under §483.10(b)(4).	An interdisciplinary team, in conjunction with the resident, resident's family, surrogate or representative, as appropriate, develops quantifiable objectives for the highest level of functioning the resident may be expected to maintain, based on the comprehensive assessment. The interdisciplinary team shows evidence in the RAP Summary or clinical record of the resident's status in triggered RAP areas and their rationale for deciding whether to proceed with care planning and that they considered the development of care planning interventions for outcome objective if identification of those steps will enhance the resident's ability to meet his/her objectives. Facility staff will use these objectives to follow resident progress. Facilities may, for some residents, need to prioritize needed care. This should be noted in the clinical record or on the plan of care. The requirements reflect the facility's responsibility to provide necessary care and services to attain or maintain the highest practicable physical, mental or psychosocial well-being, in accordance with the comprehensive assessment and plan of care. However, in some cases, a resident may wish to refuse certain services or treatments that professional staff believe may be indicated to assist the resident in reaching his or her highest practicable level of well-being. The desires of the resident should be documented in the clinical record.
C396	(2) A comprehensive care plan must be — (i) Developed within 7 days after the completion of the comprehensive assessment; (ii) Prepared by an interdisciplinary team, that includes the attending physician, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident's needs, and, to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative; and (iii) Periodically reviewed and revised by a team of qualified persons after each assessment.	 Evaluation of comprehensive care plans will consider the following: Do treatment objectives have measurable outcomes? Does the care plan reflect standards of current professional practice? Corroborate information regarding the resident's goals and wishes for treatment in the plan of care by interviewing residents, especially those identified as refusing treatment. Determine whether the facility has provided adequate information to the resident so that the resident was able to make an informed choice regarding treatment. If the resident has refused treatment, does the care plan reflect the facility's efforts to find alternative means to address the problem? A comprehensive care plan is developed within 7 days of the completion of the assessment.

TAG	REGULATION	ELEMENTS TO CONSIDER
C397	(3) The services provided or arranged by the facility must – (i) Meet professional standards of quality; and	The intent of this regulation is to assure that persons providing services are qualified to do so, that the resident's plan of care is implemented, and that those services provided meet professional standards of quality and are provided by appropriate qualified persons (e.g., licensed, certified).
		"Professional standards of quality" means services that are provided according to accepted standards of clinical practice. Standards may apply to care provided by a particular clinical discipline or in a specific clinical situation or setting. Standards regarding quality care practices may be published by a professional organization, licensing board, accreditation body or other regulatory agency. Recommended practices to achieve desired resident outcomes might also be found in clinical literature.
C398	(ii) Be provided by qualified persons in accordance with each resident's written plan of care.	The hospital has recommended practices to achieve desired resident outcomes. These may include: (a) Current manuals or textbooks on nursing, social work, physical therapy, and so forth. (b) Standards published by professional organizations such as the American Nurses' Association, the National Association of Social Work, the American Dietetic Association, the National Association of Activity Professionals, the American Medical Association, and so forth. (c) Clinical practice guidelines published by the Agency for Health Care Policy and Research. (d) Current professional journal articles.
C399	(e) <u>Discharge summary</u> . When the facility anticipates discharge a resident must have a discharge summary that includes – (1) A recapitulation of the resident's stay;	The intent of this regulation is to ensure appropriate discharge planning and communication of necessary information to the continuing care provider. A post-discharge plan of care for an anticipated discharge is done for each resident whom the facility discharges to a private residence, to another NF or SNF, or to another type of residential facility such as a board and care home or an intermediate care facility for mentally retarded individuals.
	(2) A final summary of the resident's status to include items in paragraph (b)(2) of this section, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or legal representative; and	A "post-discharge plan of care" means the discharge planning process which includes: assessing continuing care needs and developing a plan designed to ensure the individual's needs will be met after discharge from the facility into the community.
	(3) A post-discharge plan of care that is developed with the participation of the resident and his or her family, which will assist the resident to adjust to his or her new living environment.	"Anticipates" means that the discharge was not an emergency discharge (e.g., hospitalization for an acute condition) or due to the resident's death.
		"Adjust to his or her living environment" means that the post-discharge plan, as appropriate, should describe the resident's and family's preferences for care, how the resident and family will access these services, and how care should be coordinated if continuing treatment involves multiple care givers. It should identify specific resident needs after discharge such as personal care, sterile dressings, and physical therapy, as well as describe resident/care giver education needs to ensure the resident/care giver is able to meet care needs after discharge.

TAG	REGULATION	ELEMENTS TO CONSIDER
C400	§483.25 Quality of Care. Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.	Parameters of nutritional status that are unacceptable include unplanned weight loss as well as other indices such as peripheral edema, cachexia and laboratory tests indicating malnourishment (e.g., serum albumin levels).
	(i) <u>Nutrition</u> . Based on a resident's comprehensive assessment, the facility must ensure that a resident –	Weight: Since ideal body weight charts have not yet been validated for the institutionalized elderly, weight loss (or gain) is a guide in determining nutritional status. An analysis of weight loss or gain should consider the loss or gain in light of the individual's former life style as well as the current diagnosis.
	(1) Maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible; and	
C401	(2) Receive a therapeutic diet when there is a nutritional problem.	Suggested parameters for evaluating significance of unplanned and undesired weight loss are:
		<u>Interval</u> <u>Significant Loss</u> <u>Severe Loss</u>
		1 month 5% Greater than 5% 3 months 7.5% Greater than 7.5% 6 months 10% Greater than 10%
		The following formula determines percentage of loss: % of body weight loss = usual weight - actual weight / usual weight x 100.
		In evaluating weight loss, consider the resident's usual weight through adult life; the assessment of potential for weight loss; and care plan for weight management. Also, was the resident on a calorie restricted diet, or if newly admitted and obese, and on a normal diet, are fewer calories provided than prior to admission? Was the resident edematous when initially weighed, and with treatment, no longer has edema? Has the resident refused food?
		Some laboratories may have different "normals." Determine range for the specific laboratory. Because some healthy elderly people have abnormal laboratory values, and because abnormal values can be expected in some disease processes, do not expect laboratory values to be within normal ranges for all residents. Consider abnormal values in conjunction with the resident's clinical condition and baseline normal values.
		Note: There is no requirement that facilities order the tests references above.
		<u>Clinical Observations</u> : Potential indicators of malnutrition are pale skin, dull eyes, swollen lips, swollen gums, swollen and/or dry tongue with scarlet or magenta hue, poor skin turgor, cachexia, bilateral edema, and muscle wasting.

TAG	REGULATION	ELEMENTS TO CONSIDER
C401 continued	(2) Receive a therapeutic diet when there is a nutritional problem.	"Therapeutic diet" means a diet ordered by an MD/DO as part of treatment for a disease or clinical condition, to eliminate or decrease certain substances in the diet, (e.g., sodium) or to increase certain substances in the diet (e.g., potassium), or to provide food the resident is able to eat (e.g., a mechanically altered diet).
C402	§483.45 Specialized rehabilitative services. (a) Provision of services. If specialized rehabilitative services such as, but not limited to physical therapy, speech-language pathology, occupational therapy, and mental health rehabilitative services for mental illness and mental retardation, are required in the resident's comprehensive plan of care, the facility must (1) Provide the required services; or (2) Obtain the required services from an outside resource (in accordance with §483.75(h) of this part) from a provider of specialized rehabilitative services.	The intent of this regulation is to assure that residents receive necessary specialized rehabilitative services as determined by the comprehensive assessment and care plan, to prevent avoidable physical and mental deterioration and to assist them in obtaining or maintaining their highest practicable level of functional and psychosocial well being. Specialized rehabilitative services are considered a facility service and are included within the scope of facility services. They must be provided to residents who need them even when the services are not specifically enumerated in the State plan. No fee can be charged a Medicaid recipient for specialized rehabilitative services because they are covered facility services. A facility is not obligated to provide specialized rehabilitative services if it does not have residents who require these services. If a resident develops a need for these services after admission, the facility must either provide the services, or, where appropriate, obtain the service from an outside resource. For a resident with mental illness (MI) or mental retardation (MR) to have his or her specialized needs met, the individual must receive all services necessary to assist the individual in maintaining or achieving as much independence and self determination as possible. Specialized services for mental illness or mental retardation refers to those services to be provided by the State which can only be delivered by personnel or programs other than those of the nursing facility (NF) because the overall level of NF services is not as intense as necessary to meet the individuals needs. "Mental health rehabilitative services for MI and MR" refers to those services of lesser frequency or intensity to be implemented by all levels of nursing facility staff who come into contact with the resident who is mentally ill or who has mental retardation. These services are necessary regardless of whether or not they require additional services to be provided for or arranged by the State as specialized serv

TAG	REGULATION	ELEMENTS TO CONSIDER
C403	(b) Qualifications. Specialized rehabilitative services must be provided under the written order of a physician by qualified personnel.	A qualified professional provides specialized rehabilitative services for individuals under a physician's order. Once the assessment for specialized rehabilitative services is completed, a care plan must be developed, followed, and monitored by a licensed professional. Once a resident has met his or her care plan goals, a licensed professional can either discontinue treatment or initiate a maintenance program which either nursing or restorative aides will follow to maintain functional and physical status.
		"Qualified personnel" means that professional staff are licensed, certified or registered to provide specialized therapy/rehabilitative services in accordance with applicable State laws. Health rehabilitative services for MI and MR must be implemented consistently by all staff unless the nature of the services is such that they are designated or required to be implemented only be licensed or credentialed personnel.
C404	§483.55 Dental services. The facility must assist residents in obtaining routine and 24-hour emergency dental care.	This requirement makes the facility directly responsible for the dental care needs of its residents. The facility must ensure that a dentist is available for residents. It can satisfy this requirement by employing a staff dentist or having a contract/arrangement with a dentist to provide services.
		For Medicare and private pay residents, facilities are responsible for having the services available, but they may impose an additional charge for the services. Medicaid residents may not be charged.
		For all residents of the facility, if they are unable to pay for needed dental services, the facility should attempt to find alternative funding sources or alternative service delivery systems so that the resident is able to maintain his/her highest practicable level of well being.

TAG	REGULATION	ELEMENTS TO CONSIDER
C405	(a) Skilled nursing facilities. A facility – (1) Must provide or obtain from an outside resource, in accordance with §483.75(h) of this part, routine and emergency dental services to meet the needs of each resident;	§483.55(b) Nursing Facilities does not usually apply to Medicare reimbursed swing-bed residents because Medicare swing-bed residents receive skilled nursing care comparable to services provided in a SNF not a NF. If a swing-bed resident is a NF level patient, apply standard §483.55(b) as appropriate.
	(2) May charge a Medicare resident an additional amount for routine and emergency dental services;	"Routine dental services" means an annual inspection of the oral cavity for signs of disease, diagnosis of dental disease, dental radiographs as needed, dental cleaning, fillings (new and repairs), minor dental plate adjustments, smoothing of broken teeth, and limited prosthodontic procedures (e.g., taking impressions for dentures and fitting dentures).
		"Emergency dental services" includes services needed to treat an episode of acute pain in teeth, gums, or palate; broken, or otherwise damaged teeth, or any other problem of the oral cavity that requires immediate attention.
		"Prompt referral" means, within reason, as soon as the dentures are lost or damaged. Referral does not mean that the resident must see the dentist at that time, but does mean that an appointment (referral) is made, or that the facility is aggressively working at replacing the dentures.
C406	(3) Must if necessary, assist the resident –	
	(i) In making appointments, and	
	(ii) By arranging for transportation to and from the dentist's office; and	
	(4) Promptly refer residents with lost or damaged dentures to a dentist.	
C407	(b) Nursing facilities. The facility –	
	(1) Must provide or obtain from an outside resource, in accordance with §483.75(h) of this part, the following dental services to meet the needs of each resident;	
	(i) Routine dental services (to the extent covered under the State plan); and	
	(ii) Emergency dental services.	
C408	(2) Must, if necessary, assist the resident –	
	(i) In making appointments; and	
	(ii) By arranging for transportation to and from the dentist's office; and	
	(3) Must promptly refer residents with lost or damaged dentures to a dentist.	